



Pharmaceutical Waste Rule – Pharmacy Inspections

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Th-H1

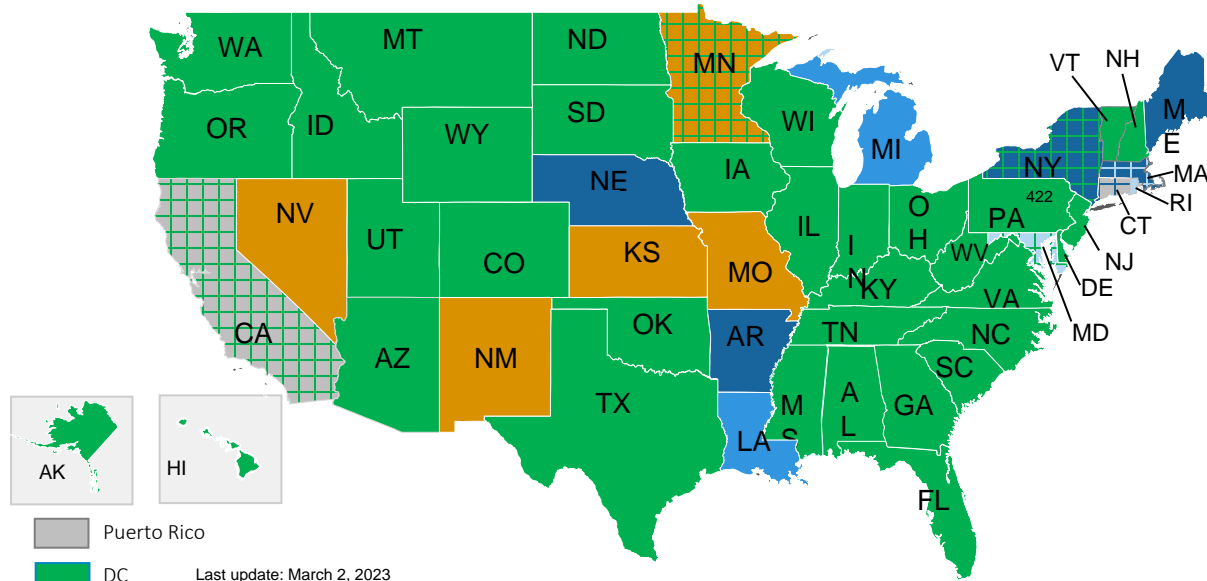
March 23, 2023



25th California Unified Program
Annual Training Conference

March 20 – 23, 2023







Anticipated Pharmaceutical Rule State Adoption




 Puerto Rico
 DC

Last update: March 2, 2023

Electronic Data =
Official Version /
Paper Copy =
Information Only

Adoption Status Key	
 Rule effective	 Early '23 (Jan – Apr)
 Adoption timeline not provided	 Mid '23 (May – Aug)
	 Late '23 (Sept– Dec)
	 2024

 State expected to adopt Nicotine mgmt. amendment first
 Line color: anticipated NRT exemption adoption date (if green lines, NRT exemption effective)
 Square color: anticipated Subpart P Subpart P adoption requires rulemaking

Note: Adoption statuses are projections and are subject to change. This map will be reviewed and updated periodically to reflect the most up to date statuses.

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“Subpart P States” – Inspections

HEALTHCARE FACILITY CHECKLIST

This checklist is to be used for all healthcare facilities that are above VSQG limits for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste or if the facility has spilled into Part 266, Subpart P, VSQG >100kg (Approximately 25-30 gallons) of waste in a calendar month or < 1 Kg. of acutely hazardous waste HWP. To convert from gallons to pounds: Amount in gallons x Specific Gravity x 8.345 = Amount in pounds

Safety Equipment User

GENERAL REQUIREMENTS

1. Has the healthcare facility notified EPA using Ohio EPA form EPA 9029 that the facility is a healthcare facility? [3745-266-502(A)] Yes No N/A

Note: The notification needs to be submitted by December 4, 2020 or within 60 days of the healthcare facility becoming subject to the rule. If a healthcare facility is an LDC, the notification can be submitted as part of the next biennial report due 3/1/2022. The notification needs to be kept of file as long as the healthcare facility is subject to the rule.

2. Has the healthcare facility disposed of hazardous waste on-site without a permit [ORC 3734.02 (E) & (F)]? Yes No N/A

3. Has the healthcare facility discharged hazardous waste pharmaceuticals to a sewer system that passes through to a publicly owned treatment works? [3745-266-500] Yes No N/A

4. Has the healthcare facility sent hazardous waste other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor? [3745-266-502(C) (ORC 3734.02 (F) (3745-266-508(A)(2)))] Yes No N/A

Note: Shipping non-creditable hazardous waste pharmaceuticals requires the use of a manifest. It may be necessary to fill out a separate generator checklist if the hazardous waste sent off-site was non-pharmaceutical hazardous waste. The facility would be in violation of ORC 324.08 (F) and possibly 3745-52-20(A) for failure to use a hazardous waste manifest, depending on the facility's generator category.

5. Have test results, waste analyses, or other determinations made to support the healthcare facility's hazardous waste determinations been retained for at least three years? [3745-266-502(J)(2)] Yes No N/A

Note: Individual determinations are not required if managing all pharmaceuticals as hazardous.

MANAGEMENT OF NON-CREDITABLE HAZARDOUS WASTE PHARMACEUTICALS (NC HWPs)

6. Does the healthcare facility ensure that all personnel managing NC HWPs are thoroughly familiar with proper waste handling and emergency procedures relevant to the personnel's responsibilities during normal facility operations and emergencies? [3745-266-502(B)] Yes No N/A

RBK:

[Facility Name/Inspection Date] (ID number) Healthcare Facility Checklist 2022 Page 1 of 6

for a non-creditable material (i.e., the waste 35-1-20 to 3745-51-24 of the 41-30 to 3745-51-35 of the length of time that the NC HWP first

Yes No N/A

structurally sound, compatible leakage, spillage, or damage reasonable conditions? [3745-266-502(A)] Yes No N/A

re. NC HWPs, or that may or so that the containers do not or explosion, or violent Yes No N/A

le. dusts, or gases in sufficient 3745-266-502(D)(2)(v) Yes No N/A

or gases in sufficient 3745-266-502(D)(3) Yes No N/A

container? [3745-266-502(D)(4)] Yes No N/A

and in a manner that 3745-266-502(D)(5) Yes No N/A

and because of the dilution stored in a separate container see numbers? [3745-266-502(D)(6)] Yes No N/A

generator and initial transporter? Yes No N/A

ret for at least three years? Yes No N/A

nd disposal restriction (1)(A)? Yes No N/A

be identified? Yes No N/A

is used? If so, did it do all the Yes No N/A

pretest or item 20 of the new manifest? [3745-266-502(E)] Yes No N/A

ected shipment, send a copy of the manifest? [3745-266-502(F)] Yes No N/A

atched shipment, transport or air in accordance with the (A)? [3745-266-502(H)(4)] Yes No N/A

[Facility Name/Inspection Date] (ID number) Healthcare Facility Checklist 2022 Page 2 of 6

the length of time that the NC HWP first Yes No N/A

the following methods: NC HWPs with the date that it certifies the date the NC HWPs, and identifying the earliest date [3745-266-502(F)(2)(ii)-(iii)] Yes No N/A

manifest, indicating that the healthcare remanifest of delivery, to the director? Yes No N/A

in the manifest or on an attached sheet in copy was not received and retaining the results of those efforts? Yes No N/A

facility does not receive a copy of the non-creditable hazardous waste if the designated facility is an alternate or operator of the alternate facility, non-creditable hazardous waste was awarded the shipment of non-creditable from the designated facility to are facility subject all of the following: Yes No N/A

manifest, indicating that the healthcare remanifest of delivery, to the director? Yes No N/A

in the manifest or on an attached sheet in copy was not received and retain the results of those efforts? Yes No N/A

its being maintained for at least three Yes No N/A

HWPs Yes No N/A

NC HWPs from an off-site healthcare following conditions met? Yes No N/A

ally under control of the same 'person' actual or other documented business healthcare facility requires that quantity generated healthcare facility operating under rules 3745-266- management of NC HWPs? [3745-266-502(G)] Yes No N/A

verage NC HWPs it receives from off- 3745-266-500 to 3745-266-510? [3745-266-502(H)(4)] Yes No N/A

Facility keeps records of shipments if 1 years? [3745-266-502(I)(4)] Yes No N/A

[Facility Name/Inspection Date] (ID number) Healthcare Facility Checklist 2022 Page 3 of 6

enter a copy of the manifest with the of the designated facility within 60 days after did the healthcare facility submit the Yes No N/A

manifest, indicating that the healthcare remanifest of delivery, to the director? Yes No N/A

in the manifest or on an attached sheet in copy was not received and retaining the results of those efforts? Yes No N/A

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Facility keeps records of shipments if 1 years? [3745-266-502(I)(4)] Yes No N/A

[Facility Name/Inspection Date] (ID number) Healthcare Facility Checklist 2022 Page 4 of 6

2. Identify and mark its hazardous waste materials? Yes No N/A

number of one hundred-thirteen in with the following words and Federal Law Prohibits improper use or public safety authority of y, Healthcare Facility's or other: Healthcare Facility's or Manifest Tracking Yes No N/A

marker marking example: Not with EPA hazardous waste 8, D010, and D011, where system may be placed or other healthcare facility placed or other transporter? Yes No N/A

F supports non-creditable hazardous waste pharmaceuticals or ect to 40 C.F.R. Part 262 subpart H. Any person who imports non- related hazardous waste pharmaceuticals is subject to 40 C.F.R. distributor may not accept imported non-creditable hazardous the pharmaceuticals unless the healthcare facility or reverse- interim standards that allows the healthcare facility or reverse [3745-266-504 (B) and (C)]

HAZARDOUS WASTE PHARMACEUTICALS (PC HWPs)

HWPs from an off-site healthcare following conditions met? Yes No N/A

nder control of the same 'person' or other documented business healthcare facility requires that quantity generated healthcare facility operating under rules 3745-266- management PC HWPs? [3745-266-504 (B) and (C)] Yes No N/A

erating under rules 3745-266- management PC HWPs? [3745-266-504 (B) and (C)] Yes No N/A

er the PC HWPs it receives from 3745-266-500 to 3745-266-510? Yes No N/A

ords of shipments it receives 266-503(I)(4) Yes No N/A

of shipping papers and lists of PC HWPs for at least three Yes No N/A

of regulations for any PC HWPs' manifest? Yes No N/A

[Facility Name/Inspection Date] (ID number) Healthcare Facility Checklist 2022 Page 5 of 6

of days after Yes No N/A

re pharmaceuticals to a foreign destination (, except the manifesting requirement of 40 use that records potentially creditable (C) of this rule in lieu of 40 C.F.R. Part 262 pharmaceuticals enter Ohio, the hazardous 3745-266-500 to 3745-266-510 [3745-266-502(J)(2)] Yes No N/A

[Facility Name/Inspection Date] (ID number) Healthcare Facility Checklist 2022 Page 6 of 6




Registration/Notification

- One-time notification that we are a healthcare facility (HCF) operating under 266 Subpart P within 60 days of rule's effective date
- Maintain notification on file (readily available during inspections)

OMB# 2050-0024; Expires 04/30/2024

United States Environmental Protection Agency
RCRA SUBTITLE C SITE IDENTIFICATION FORM



1. Reason for Submittal (Select only one.)

<input checked="" type="checkbox"/>	Obtaining or updating an EPA ID number for on-going regulated activities (Items 10-17 below) that will continue for a period of time.
<input type="checkbox"/>	Submitting as a component of the Hazardous Waste Report for _____
<input type="checkbox"/>	Site was a TSD facility, a reverse distributor, and/or generator of hazardous waste, > 1 kg of acute hazardous waste, or > 100 kg of acute hazardous waste, during more months of the reporting year (or State equivalent LCRA reporting year).
<input type="checkbox"/>	Notifying that regulated activity is no longer occurring at this Site
<input type="checkbox"/>	Obtaining or updating an EPA ID number for conducting Electronic Monitoring
<input type="checkbox"/>	Submitting a new or revised Part A (permit) Form

D. Pharmaceutical Activities

<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	1. Operating under 40 CFR Part 266, Subpart P for the management of hazardous waste pharmaceuticals—if “Yes”, mark only one. Note: See the item-by-item instructions for definitions of healthcare facility and reverse distributor.
<input type="checkbox"/>	a. Healthcare Facility
<input type="checkbox"/>	b. Reverse Distributor
<input type="checkbox"/> Y <input checked="" type="checkbox"/> N	2. Withdrawing from operating under 40 CFR Part 266, Subpart P for the management of hazardous waste pharmaceuticals. Note: You may only withdraw if you are a healthcare facility that is a VSQG for all of your hazardous waste, including hazardous waste pharmaceuticals.



“Does Not Sewer Hazardous Waste Pharmaceuticals”



Do not rinse or dispose of hazardous waste or pharmaceuticals down the drain.

These items include:

- Prescription medications
- Over-the-counter drugs
- Items containing residual pharmaceuticals
- Controlled substances
- Residues of pharmaceuticals remaining in empty containers
- Potentially hazardous materials

The location of a spill kit is listed on your EPP Summary.

Additional spill response information can also be reviewed in the store Hazardous Waste Contingency Plan located on Store Resources under:

Safety and Environmental > Environmental



To view this sign in additional languages, please scan the QR code.

In the event of a spill, call the CVS Health Safety Hotline at 1-888-464-2960.



Management Stds – Non-Creditable Hazardous Waste Pharmaceuticals

Does the healthcare facility ensure that all personnel managing NC HWP's are thoroughly familiar with proper waste handling and emergency procedures relevant to the personnel's responsibilities during normal facility operations and emergencies?

Course Objectives

At the conclusion of this course you will be able to:

- Follow the CFRxWeekly Process for non-saleable items collected in an Akrobin
- Identify processing steps for non-inventory items before placing in hazardous waste totes
- Identify key tasks in preparation for and completing hazardous waste pick-up
- Describe how to set up a hazardous waste tote
- Respond appropriately to hazardous waste regulatory visits
- Locate resources and support



Management Stds – Non-Creditable Hazardous Waste Pharmaceuticals

Ensures that all personnel that manage non-creditable HWP are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies



Emergency Procedures Plan

Retail Locations



Emergency Procedures Plan Summary

Store Information

Store Number: _____
Store Address: _____
Store Phone Number: _____
Contact Name (Store Manager): _____
Phone Number (cell phone): _____

Emergency Coordinator Information:

Contact Name: **3E Company**
Phone Number: **(888) 464-2960** (24 Hour Hotline)


Emergency Response Information

Fire Department: 911
Locations of Fire Extinguishers: _____
Locations of Fire Alarms: _____
Locations of Spill Cleanup Materials: _____

Designated outdoor rally point for your store is: _____
Designated indoor rally point for your store is: _____

24 Hour CVS Health Safety Hotline
(888) 464-2960

This Plan Summary must be posted by an out-dialing telephone close to each hazardous waste storage area (e.g., Pharmacy, Photo, stock room, and Waste Clinic as applicable).



Events and Their Codes that Require Immediate Evacuation:

- Fire - Code 1**
All colleagues, customers, patients and vendors must evacuate immediately and meet at the designated outdoor rally point.
- Bomb Threat - Code 1**
All colleagues, customers, patients and vendors must evacuate immediately and meet at the designated outdoor rally point.
- All Audible Store Alarms - Code 1**
All colleagues, customers, patients and vendors must evacuate immediately and meet at the designated outdoor rally point.

Events and Their Codes that Normally Do Not Require Immediate Evacuation:

- Power Failure - Code 2**
All colleagues should meet at the designated indoor rally point.
- Await instructions from Manager on duty.
- Earthquake - Code 2**
- Shelter under a sturdy object (e.g., a table or desk) and away from windows.
- Await instructions from Manager on duty.
- Hazardous/Toxic/Reactive - Code 2**
- All colleagues should meet at the designated indoor rally point.
- Await instructions from Manager on duty.
- Spill or Release of Chemical or Hazardous Waste (Contingency Plan)**
- Restrict colleagues, customers, patients and vendors from the area.
- Notify the Store Manager listed on the left or the Manager on duty.
- Call the 24-hour CVS Health Safety Hotline and follow instructions.
- Workplace Violence - Code 2**
- Instructions will be provided by the Manager on duty based on the nature and location of event.

Other Events

- Medical Emergency (colleague, customer patient or vendor)**
- Call 911
- Await instructions from Manager on duty.
- Miscellaneous**
- Notify Manager on duty and assist instructions.



Management Stds – Non-Creditable Hazardous Waste Pharmaceuticals

This label is NOT to be used as a DOT shipping label - see your State/cycle technician for clarification

Non-Viable Hazardous Waste Pharmaceuticals

Physical State:
 Solid Liquid

Accumulation Start Date: _____
 CVS Store #: _____
 Store Address: _____

Contents:

Loose Pills Pharmaceutical spill clean-up materials & materials from cleaning pharmaceutical equipment & utensils

Empty containers (closed) that once contained pharmaceuticals in the Warfarin family Other: _____

Trace chemotherapy waste Empty vaccine vials

MAY CONTAIN THE FOLLOWING:
 Hazardous Waste: D001, D002, D006, D007, D008, D011, D021, D024, P012, U010, U014, U015, U016, U117, U122, U126, U127, U128, U104, U105, U106, U108, U109, U104, U105, P003, P015, Hazardous Waste Pharmaceuticals (where applicable)
 State Regulated Waste: H11, W102, W101, W101, W101

REMOVE ALL PROTECTED HEALTH INFORMATION PRIOR TO PLACEMENT IN COLLECTION CONTAINER.
THIS CONTAINER MUST REMAIN CLOSED AT ALL TIMES.
 HAZARDOUS WASTE - FEDERAL LAW PROHIBITS IMPROPER DISPOSAL.
 NOTE: THIS LABEL IS NOT TO BE USED AS A DOT SHIPPING LABEL - SEE YOUR STATE/CYCLE TECHNICIAN FOR CLARIFICATION.



CONTAINER MANAGEMENT

- Are NC HWPs placed in containers that are structurally sound, compatible with the contents, and that lack evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions?
- Are containers of NC HWPS closed and secured in a manner that prevents unauthorized access to the contents?
- Are containers labeled or clearly marked with the phrase "Hazardous Waste Pharmaceuticals?"
- Are containers accumulated on-site for one year or less?



Management Stds – Non-Creditable Hazardous Waste Pharmaceuticals

MANIFEST REQUIREMENTS

- *Are all NC HWPs shipped off-site accompanied by a manifest (U.S. EPA Form 8700-22)?*
- *Does each manifest designate at least one facility which is permitted to handle the waste?*
- *Have the manifests been signed by the generator and initial transporter?*
- *Are signed copies of manifests being retained for at least three years?*
- *Has the healthcare facility complied with land disposal restriction requirements?*
- *If the healthcare facility did not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days after being accepted by the transporter, did the healthcare facility submit an exception report?*
- *Are signed copies of exception reports being maintained for at least three years?*

9a. HM	9b. U.S. DOT Description (including Proper Shipping Name, Hazard Class, ID Number, and Packing Group (if any))	10. Containers		11. Total Quantity	12. Unit Wt./Vol.	13. Waste Codes		
		No.	Type			PHRM	PHRM	D005
X	1. UN3249, Waste Medicine, solid, toxic, n.o.s. (Chromium, Selenium), 6.1, PG II, ERG#151	1	CF	00010	P	D007	D008	D010
X	2. UN2810, Waste Toxic, liquids, organic, n.o.s. (M-Cresol, Thimerosal), 6.1, PG II, ERG#153	1	CF	00002	P	D018	D007	D024



Management Stds – Non-Creditable Hazardous Waste Pharmaceuticals

Pharmaceutical Spill Cleanup Materials	<p>When handling a pharmaceutical spill cleanup, contact the CVS Health Safety Hotline at 888-464-2960 if:</p> <ul style="list-style-type: none">• The spill is larger than you typically handle, or;• You require assistance on the proper safety/protective equipment to wear. <p>NEVER place spill cleanup materials in the trash or rinse down the drain.</p> <p>Spill cleanup supplies are available in the Hazardous Waste collection area.</p> <ul style="list-style-type: none">• Note: Additional spill cleanup materials are available at spill stations on the sales floor for CVS Pharmacy in Target locations.	<ol style="list-style-type: none">1. Place all cleanup materials used to handle the spill in a hazardous waste bag.2. For a liquid pharmaceutical spill, place sufficient absorbent to completely soak up all liquids in the bag if the liquid is not self-contained.3. Seal the hazardous waste bag completely.<ul style="list-style-type: none">• Place the sealed hazardous waste bag containing liquids in a second hazardous waste bag to prevent liquids from leaking.4. Label the bag to clearly identify the pharmaceutical contained inside.5. Place the labeled bag in the Hazardous Waste "PHARMACY" tote.
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SPILLS

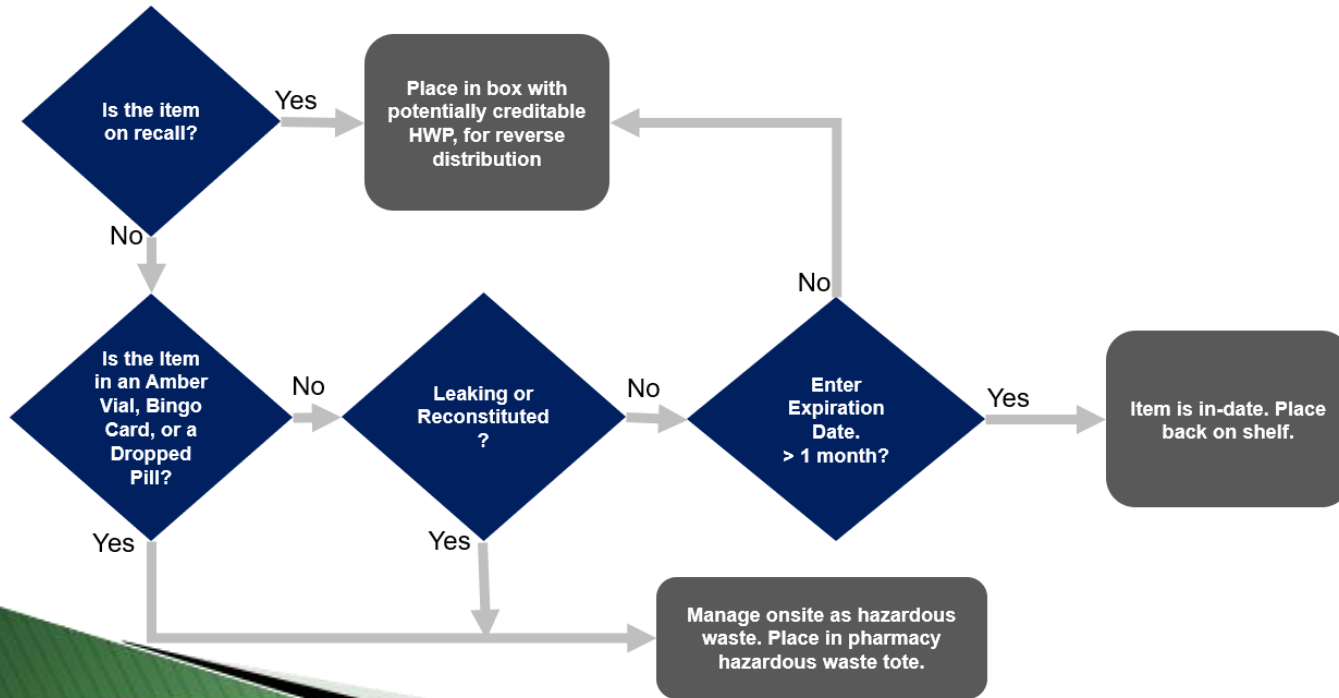
- *Has the healthcare facility immediately contained all spills of NC HWPs and manage the spill clean-up materials as NC HWPs?*
- *Has the healthcare facility immediately contained all spills of potentially creditable hazardous waste pharmaceuticals and managed the spill cleanup materials as non-creditable hazardous waste pharmaceuticals?*



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Management of Potentially-Creditable Hazardous Waste Pharmaceuticals



- Logic imbedded in the pharmacy scanning system
- Potentially creditable HWP are sent to reverse distributor via common carrier



Shipping Potentially Creditable Hazardous Waste Pharmaceuticals

RECORDKEEPING

- *Has the healthcare facility retained copies of shipping papers and confirmation of deliveries for all shipments of PC HWP's for at least three years?*
- *If delivery confirmation is not received within thirty-five calendar days after the date that the shipment of PC HWP's was sent, did the healthcare facility contact the carrier and the reverse distributor to report delivery confirmation was not received and to determine the status of the PC HWP's?*

Box Status	Received Boxes	Issued 222 Forms		
PROCESSED BOXES				
Box Label	Client Unique Id	Program	Type	Units
85008553500040	0000009517	CVS	RX	157
85008553500041	0000009518	CVS	CIII-V	59
85008553500039	0000009514	CVS	CII	5
85008553500036	0000009475	CVS	CII	9
85008553500037	0000009476	CVS	RX	91
85008553500038	0000009477	CVS	CIII-V	127
85008553500034	0000009435	CVS	CIII-V	70
85008553500035	0000009436	CVS	RX	113
85008553500033	0000009434	CVS	CII	2
85008553500030	0000009392	CVS	CII	8
85008553500031	0000009394	CVS	RX	50
85008553500032	0000009395	CVS	CIII-V	50





Any Questions?

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BREAK TIME!

