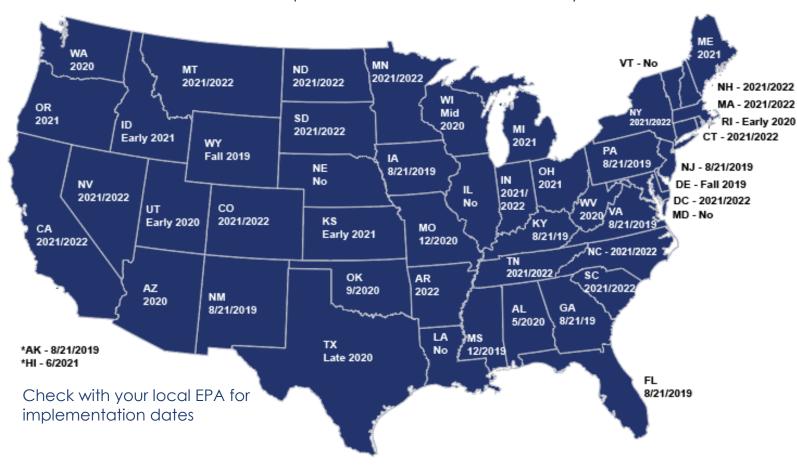
PHARMALINK CAN HELP YOU BE COMPLIANT WITH THE NEW EPA RULE!

Pharmalink can:

- Separate your Potentially Creditable Hazardous and Non-Hazardous Waste Pharmaceuticals from your other hazardous waste pharmaceuticals.
- Tell you which waste stream your Non-creditable Hazardous Waste Pharmaceuticals should be placed.
- Prepare the proper shipping documents for your Potentially Creditable
 Hazardous and Non-Hazardous Waste Pharmaceuticals.
- Make sure you avoid any state and federal penalties for sending noncreditable Hazardous Waste to PharmaLink.

PharmaLink will be compliant August 2019.

REMEMBER... Each aspect of the amendment has a different effective date and those effective dates are dependent on the state in which you are located:





PharmaLink can help you be compliant with the new EPA rule: 40 CFR Part 266 Subpart P

ARE YOU A ...?

- Wholesale Distributor
- Third-Party Logistics Provider (3PL)
 that Serves as a Forward Distributor
- Military Medical Logistics Facility
- Hospital
- Psychiatric Hospital
- Ambulatory Surgical Center
- Health Clinic
- Physician's Office
- Chiropractor

- Optical And Dental Provider
- Long-Term Care Facility
- Ambulance Service
- Pharmacy
- Long-Term Care Pharmacy
- Mail-Order Pharmacy
- Retailer Of Pharmaceuticals
- Veterinary Clinic Or Hospital

If you are any of the above facilities and you distribute, sell or dispense

HAZARDOUS prescription or over-the-counter pharmaceuticals, then the

EPA has defined you as a HEALTHCARE FACILITY.





DEPENDING ON YOUR HAZARDOUS WASTE GENERATOR CATEGORY, YOU MAY BE ABLE TO OPT OUT OF SUBPART P PER 266.504

To determine your hazardous waste generator category:

- Very Small Quantity Generator (VSQG)
- Small Quantity Generator (SQG)
- Acute HW = P-Listed Waste
- Large Quantity Generator (LQG)
- Non-Acute HW = U Listed or Characteristic D Codes

| Generator Status | Acute HW Generated Monthly | Non-Acute HW Generated Monthly |
|------------------|----------------------------|--------------------------------|
| VSQG | ≤ 1 kg (and) | ≤ 100 kg |
| SQG | < 1 kg (and) | > 100 kg and < 1000 kg |
| LQG | > 1 kg (or) | ≥ 1000 kg |

If you are a VSQG you can opt out of participating in Subpart P BUT YOU MUST:

- o Determine the amount of Hazardous Waste you generate on a monthly basis
- o Include any Hazardous Waste Pharmaceuticals sent to a Reverse Distributor
- o Follow 40 CFR §262.14 (VSQG)

If you are a VSQG and you DO NOT opt-out of Subpart P then you have to comply with:

- EPA Notification §266.502
- Accumulation Time Limits §266.502 (f) & §266.501 (f)
- Training Personnel §266.502 (b)
- Containers for Accumulation §266.504 (a)
- Labeling Containers §266.504 (c)
- DEA/HWP Exemption §266.506
- Biennial Reporting §266.503 (a)
- Rejected Shipments §266.502 (h)
- Waste Manifest Requirements §266.502 (h) (i) (j)
- Delivery Confirmation §266.503 (e)(i)
- Spill Response §266.503 (f) & §266.502 (k)
- Recordkeeping §266.503

If you opt-out of Subpart P you must still comply with:

- Nicotine Amendment
- Send PCHW to an RD §266.504
- Sewering Ban Rule §266.505
- Empty Containers are now considered Non-Hazardous §266.507

VSQG's must send potentially creditable Hazardous Waste pharmaceuticals to an RD and non-creditable Hazardous Waste pharmaceuticals to a Hazardous Waste Disposal Facility.

If you have Potentially Creditable Hazardous Waste Pharmaceuticals that are:

- In the original manufacturer's packaging
- Prescription
- Undispensed
- Less than 1 year past expiration date

...Then, it can be sent to PharmaLink for evaluation based on the manufacturer's return policy and credit determination.

If you have sharps, syringes, sharp/syringe combos without pharmaceuticals and medical waste...

...Then, it must be sent to a medical waste disposal facility.

If you have non-creditable Hazardous Waste Pharmaceuticals, such as:

- Pharmaceuticals in a broken or leaking container
- Repackaged Pharmaceuticals
- Dispensed Pharmaceuticals
- Pharmaceuticals that have been expired for over one (1) year
- Investigational new drugs
- Contaminated PPE
- Floor sweepings
- Clean-up Materials

...Then, it must be sent to a TSDF (Transfer, Storage and Disposal Facility) that accepts Hazardous Waste for destruction.

IF YOU ARE A VSQG THAT OPTS IN TO PARTICIPATING IN SUBPART P, A SQG OR A LQG, YOU MUST:



NOTIFICATION

Notify the EPA you are a healthcare facility operating under Subpart P.



TRAINING

Train your personnel that will be managing your non-creditable hazardous waste.



WASTE AND WASTE STREAM DETERMINATION

Determine whether your noncreditable waste is hazardous or medical waste. If hazardous, determine which waste stream.



CONTAINER TYPE

Store non-creditable hazardous waste in a container that will be compatible with its contents.



LABELING

Label containers storing noncreditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals."



STORAGE

Maximum on-site accumulation time: One (1) year. You must have a separate accumulation area and maintain inventory of non-creditable hazardous waste.



REPORTING

Biennial reporting is required.



RECORDKEEPING

Must keep a copy of the manifest for each shipment of non-creditable hazardous waste for three (3) years.