# Interim Pharmaceutical Waste Policy

From Ecology's Hazardous Waste and Toxics Reduction Program

# Pharmaceutical Waste Management in Healthcare

Since 2008, the Washington Department of Ecology (Ecology) has offered healthcare facilities a regulatory option called the "Interim Enforcement Policy" (IEP) for pharmaceutical waste. This was done in an effort to make managing waste pharmaceuticals easier and ensure a safe waste management system protective of human health and the environment. Ecology wrote the IEP in 2008 because the Environmental Protection Agency (EPA) was planning to announce new regulations for the management of this type of waste.

In anticipation of a new federal rule from EPA, Ecology is updating this policy. This revised policy will give hospitals, clinics, pharmacies, veterinarians, dentists, and other businesses options for how they can dispose of leftover and other unused medications. Hopefully, this will make it easier for healthcare facilities to handle pharmaceutical waste in compliance with the law. This revised policy replaces the policy from 2008 and will be in effect until state pharmaceutical rules are adopted.

Ecology will continue to use enforcement discretion and won't enforce specified parts of the dangerous waste regulations at eligible businesses that manage pharmaceutical wastes according to this policy. This should make it easier for healthcare facilities to manage pharmaceutical wastes. Facilities that don't follow these guidelines will be subject to all applicable sections of the dangerous waste regulations. The dangerous waste regulations are located in Chapter 173-303 of the Washington Administrative Code (WAC).

## Why is the policy changing?

EPA recently proposed new requirements for managing hazardous waste pharmaceuticals. You can find these proposed requirements in the September 25, 2015 Federal Register (Vol. 80 Federal Register 58014). These new requirements include a ban on disposing of pharmaceuticals down the toilet or drain.

Ecology is currently looking at the proposed requirements and determining how to adapt them for Washington State. The federal proposal has not been finalized and may still change slightly but Ecology believes the final federal rules will look very similar to the proposal. Ecology will not adopt a final state rule until EPA finalizes the new federal rules. We expect to propose new draft state rules in 2017.

This revised policy is intended to provide regulated facilities an opportunity to begin using EPA's proposed regulations early if they choose to do so. It allows healthcare facilities to accumulate dangerous waste pharmaceuticals and send them for off-site treatment and disposal. Facilities are not required to follow this policy and can choose to follow the dangerous waste regulations for their pharmaceutical wastes. All other existing regulatory options, such as the state's Conditional Exclusion, are also still available.

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When new state pharmaceutical waste regulations are finalized, this policy will be withdrawn and will no longer be in effect. All facilities will need to follow the new regulations at that time.

## Why is the policy needed?

The presence of pharmaceuticals in the environment is a worldwide concern. Current wastewater treatment technology does not remove all pharmaceuticals. Flushing medicines down the sewer, disposing of pharmaceuticals in sharps containers, or sending regulated wastes to the landfill all contribute to the contamination of our groundwater, surface water, and drinking water.

Many waste pharmaceuticals designate as either federal hazardous waste under the federal Resource Conservation and Recovery Act (RCRA) or as Washington state-only dangerous waste. These wastes need special handling, management, and disposal in order to protect workers and the environment. This policy will make it easier for healthcare facilities to meet those special requirements. In this document, the term "dangerous waste" includes both RCRA hazardous waste and state-only dangerous waste unless otherwise specified.

Healthcare facilities and pharmacies that generate dangerous waste pharmaceuticals have reported difficulty complying with the dangerous waste regulations, including:

- Concerns that healthcare workers' primary focus is to provide care for patients and not waste regulations.
- Challenges designating thousands of drug formulations.
- Challenges with specific active pharmaceutical ingredients that are heavily regulated in very small amounts.
- Difficulty in complying with both the waste regulations and regulations of other agencies, such as the federal Drug Enforcement Administration (DEA).

This policy provides an option to the existing rules for on-site accumulation of pharmaceutical waste. Any pharmaceutical waste not managed according to this policy is subject to full regulation under the dangerous waste regulations.

## What does the policy cover?

The policy covers all dangerous waste pharmaceuticals, defined as "drugs" by the Revised Code of Washington (RCW) 69.04.009. Facilities may not use this policy for non-pharmaceutical waste (including disinfectants), radioactive pharmaceutical waste, or anesthesia gases.

## Who can use the policy?

Facilities that are eligible to follow this policy include:

- **Patient care facilities**
  Hospitals, acute care facilities, outpatient surgery centers, practitioner offices, clinics, dental offices, nursing units, ambulatory clinics, long-term care facilities, and veterinary care facilities.
- **Retail Pharmacies**
  Businesses that dispense or sell over-the-counter or prescription pharmaceuticals to the consumer.

Facilities that are not allowed to use this policy include:

- **Unlicensed facilities**
  Facilities not authorized by the Washington State Board of Pharmacy (BOP) to dispense and manage pharmaceuticals.
- **Drug manufacturers**
  Businesses that prepare, derive, manufacture, or produce pharmaceuticals from raw materials. This does not include compounding in a pharmacy.
- **Drug wholesalers**
  Businesses that sell or distribute for resale pharmaceuticals to any entity other than the consumer.
- **Reverse distributors**
  Businesses taking back creditable pharmaceuticals for credit.
- **Research laboratories**

## What benefits does following the policy offer?

Following the policy provides a number of benefits, including simplifying your recordkeeping and saving time and money. You can:

- Create a waste profile based on the pharmaceutical waste you produce over a minimum three-month period instead of continuously designating each pharmaceutical under WAC 173-303-070(3).
- Send creditable pharmaceuticals to a reverse distributor for evaluation without a waste profile.
- Accumulate pharmaceutical waste on site for up to 180 days, even if your business is a Large Quantity Generator (LQG) and has to send other types of waste for disposal every 90 days. **Please note: satellite accumulation of pharmaceutical waste is not allowed.**
- Generate or accumulate any amount of pharmaceutical wastes on site. The Quantity Exclusion Limits don't apply to pharmaceutical waste managed under this policy.
- Avoid counting pharmaceutical waste toward your generator status.
- Don't report pharmaceutical waste on your Ecology Dangerous Waste Annual Report.

## What do I need to do to use this policy?

Eligible facilities (see page 3) need to do six things to be in compliance:

### 1. Profile your pharmaceutical waste and send it to Ecology

A waste profile is a summary of the pharmaceutical waste your facility generates, the applicable waste codes, and the proportion of each. You can prepare this summary based on your generator knowledge.

A waste profile might look like this:

| Waste Code | Waste Description | Minimum % of Pharmaceutical Waste (by weight) | Maximum % of Pharmaceutical Waste (by weight) |
|---|---|---|---|
| P001 | Warfarin (concentration > 0.3%) | 2 | 5 |
| P012 | Arsenic trioxide | 1 | 5 |
| P075 | Nicotine | 1 | 5 |
| U010 | Mitomycin | 5 | 10 |
| U058 | Cyclophosphamide | 5 | 15 |
| D001 | Silver nitrate | 1 | 3 |
| D009 | Mercury | 10 | 25 |
| D013 | Lindane | 5 | 10 |
| --- | Conditionally excluded state-only pharmaceutical waste (WAC 173-303-071(3)(nn)) | 22 | 70 |

You must update your waste profile at least once every three years. You must also update your waste profile whenever you make significant changes to your facility's operations, even if it's been less than three years since your last update.

You must send your initial waste profile to Ecology, but not updated profiles. The current version of your waste profile must be kept on site and available for inspection. More information about creating waste profiles is available in Ecology's *Profiling and Notification Fact Sheet*, publication #07-04-026.

### 2. Notify Ecology you are going to follow the policy instead of the full Dangerous Waste Regulations

Use the notification form provided in Ecology's *Profiling and Notification Fact Sheet*, publication #07-04-026. Your pharmacy manager and environmental manager must both sign the notification form and you must include your initial waste profile.

Send the documents to:

Department of Ecology
Hazardous Waste and Toxics Reduction Program
P2 & Regulatory Assistance
PO Box 47600
Olympia WA 98504-7600

### 3. Train your staff about the policy and how to handle pharmaceutical wastes properly

Train your staff about their responsibilities at your facility, both during normal operations and during emergencies. You must train your staff in the following areas:

- Proper waste handling
- Recordkeeping
- Emergency procedures

### 4. Follow certain standards for accumulating pharmaceutical waste

You must accumulate and store pharmaceutical wastes so that they do not get released to the environment due to a spill or other accident. You must also provide reasonable protection for safety, security, and the environment. To do this, you must:

- Place absorbent material in the bottom of containers storing liquid waste.
- Use storage containers that
  - Are compatible with their contents.
  - Are structurally sound.
  - Don't show evidence of leaks, spills, or damage that could cause leakage under reasonable foreseeable circumstances.
- Not mix or store incompatible wastes in the same container.
- Keep containers closed unless adding or removing waste.
- Keep spill cleanup materials and personal protective equipment on site.
- Label containers with the words "Hazardous Waste Pharmaceuticals" or "Dangerous Waste Pharmaceuticals."
- Label containers with all appropriate risk labels such as "Ignitable," "Corrosive," or "Toxic."
- Label containers with the first date an item of pharmaceutical waste is placed in the container.
- Limit accumulation to 180 days. **Satellite accumulation is not allowed under this policy**.

### 5. Dispose of pharmaceutical waste as required by the policy

Pharmaceutical waste not managed according to this policy revert back to management requirements in the dangerous waste regulations.

If you want to use this policy, you must follow the disposal requirements below, regardless of your generator status. You must:

- Keep all pharmaceutical waste, including partially administered controlled substances, out of the sewer.
- Send pharmaceutical waste for incineration.
  - Send your pharmaceutical waste to a RCRA-permitted incinerator. Wastes that cannot be incinerated per the Land Disposal Restrictions (LDR), such as mercury, must be segregated and sent to a permitted treatment, storage, and disposal facility (TSD).

        - If you manage your state-only dangerous waste pharmaceuticals under the Conditional Exclusion, located in WAC 173-303-071(3)(nn), you must segregate and manage it separately.
        - If a waste container has both RCRA hazardous and state-only pharmaceutical waste items commingled together, you must manage it as if it is all RCRA waste. Even one RCRA waste item in a container means the entire container is managed as RCRA waste.
    - Ship wastes to a permitted incinerator using a Uniform Hazardous Waste Manifest.

If you manage your waste under the dangerous waste regulations instead of this policy, you must:

- Keep all pharmaceutical waste, including partially administered drugs, out of the sewer.
- Send pharmaceutical waste to a permitted TSD on a Uniform Hazardous Waste Manifest, except:
    - Small quantity generators are not required to use a manifest and have additional disposal options as listed in WAC 173-303-070(8)(b)(iii).
    - State-only pharmaceutical waste eligible to be managed under the Conditional Exclusion, located in WAC 173-303-071(3)(nn) must be segregated and managed separately.
- You must count the waste toward your generator status and report annually as described in WAC 173-303-060(5).

#### 6. Keep appropriate records

You need to keep the following documents on site for at least five years and be able to produce them if needed during an inspection:

- Current and previous waste profiles.
- Copy of your pharmaceutical waste notification to Ecology.
- Uniform Hazardous Waste Manifests.
- Reverse distributor inventory records.
- All appropriate transfer paperwork for the destruction of controlled substances, including a Form 222 for Schedule II pharmaceuticals and an inventory for all other schedules.

## Can I treat pharmaceutical waste and still use the policy?

Pharmaceuticals treated on site and managed under this policy must follow WAC 173-303-170 with the following exceptions:

- You must send treatment residues, including canisters and cartridges, to a RCRA-permitted incinerator. (Treatment residues, including canisters and cartridges managed under the state-only Conditional Exclusion (WAC 173-303-071(3)(nn) may instead be incinerated according to the exclusion conditions.)
- Separate treatment logs are not required as long as the pharmaceuticals treated are captured on a waste profile (as explained above).
- Treatment of pharmaceutical waste managed under this policy does not need to be counted and reported; this includes treatment residues.

If you do not follow these specific requirements, you must follow all the requirements under WAC 173-303-170, including logging, counting, and reporting prior to treatment, and designating post-treatment, counting and reporting the residue.

**NOTE: All dangerous waste pharmaceuticals managed and/or treated under this policy must ultimately be incinerated unless prohibited by the LDRs.**

These publications will help you understand how to comply with the regulations while treating your waste:

- *Treatment by Generator: Pharmaceutical Waste*, Ecology publication # 14-04-009
- *Small Quantity Generators Treating Dangerous Waste*, Ecology publication #14-04-004

## What is dual waste* and what do I do with it?

You can manage your dual waste (defined on page 11) either under this policy or under the dangerous waste regulations. If you are managing your dual waste under the policy, and the waste:

- Is regulated under RCRA, send the waste to a RCRA-permitted facility that is also permitted to accept infectious waste. A medical waste incinerator does not meet this requirement.
- Is regulated solely as state-only dangerous waste, you can send the waste to a facility that is permitted to accept infectious wastes and that is either:
  - A RCRA-permitted facility, or
  - An incinerator that meets the requirements of the Conditional Exclusion in WAC 173-303-071(3)(nn). This includes municipal solid waste incinerators and some other types of incinerators.

**NOTE: All dual wastes managed under this policy must ultimately be incinerated unless prohibited by the LDRs.**

You must make sure your dual wastes are transported in compliance with DOT requirements for hazardous and infectious materials.

## What about DEA controlled substances?

You must manage all of your pharmaceutical waste according to this policy or according to the dangerous waste regulations, even if those pharmaceuticals are also listed on a schedule of controlled substances by the DEA.

If you are going to manage your controlled substance wastes under this policy, you must:

- Follow all DEA regulations for controlled substances, including regulations covering collection, storage, on-site management, transportation, destruction, and final disposal. This includes generators who are treating their own controlled substance wastes.
- Not dispose of controlled substance wastes to the sewer.

- Ensure that controlled substance wastes are incinerated at one of the following types of facilities:
  - A permitted large municipal waste combustor. (These facilities are subject to either Title 40 Code of Federal Regulations (CFR) Part 60, subparts Ea and Eb or to Part 62, subpart FFF; whichever is applicable.)
  - A permitted small municipal waste combustor. (These facilities are subject to either Title 40 CFR Part 60, subparts AAAA and BBBB or to Part 62, subpart JJJ; whichever is applicable.)
  - A RCRA-permitted incinerator.

You also have the option to send controlled substances to a DEA-licensed reverse distributor. This applies to both creditable and non-creditable controlled substances. If you do send your controlled substance wastes to a reverse distributor, you must ensure that the reverse distributor manages the controlled substance wastes as described above.

## Can anything go down the drain to the sewer?

**No dangerous waste pharmaceutical can go to the sewer.**
**This includes partially administered controlled substances.**

You can check with your local wastewater discharge and permit authority (either your local public works department or Ecology's Water quality Program) for approval to put *non-dangerous* waste solutions down the drain. Some common examples of non-dangerous waste IV solutions include saline, dextrose, and sterile water. Many lactated ringers would not designate, however some solutions with higher concentrations would be dangerous waste.

## What about containers that might still have medicine in them?

Containers that once held pharmaceuticals may also be pharmaceutical waste. Disposal requirements are based on whether the container is considered "empty" or not.

Examples may include residues in "empty" dispensing and unit-dose containers. A dispensing container includes:

- A bottle, vial, or ampule not to exceed one liter or one thousand pills.
- A unit-dose container (e.g., a unit dose packet, cup, wrapper, or blister pack).
- A unit-dose delivery device (such as a patch).

These containers are considered empty and the residues are not regulated as a dangerous waste if the following conditions are met:

- You have removed all pharmaceuticals from the container using common practices to remove materials from that type of container.
- Before disposing of any dispensing bottle or unit-dose container that is an original manufacturer's product package, you must destroy the container so as to prevent further use of the container.

Examples include:

- The wrapper and backing from a nicotine patch administered to a patient. The wrapper and backing may be placed in a solid waste container.
- The blister pack of a lozenge administered to a patient. An empty blister pack may be placed in a solid waste container.
- A paper cup used to transport and administer a patient's pills. The empty cup may be placed in a solid waste container.

### Empty syringes

A syringe is considered empty when its plunger has been *fully* depressed and the contents of the syringe has been *fully* dispensed. Empty syringes are not regulated as a dangerous waste and the weight of the empty syringe is not counted toward generator status. Examples of empty syringes include:

- A syringe that contained morphine is considered "empty" when the contents have been fully administered to the patient by fully depressing the plunger. Manage this syringe as solid waste.
- A syringe that contained epinephrine is considered "empty" when the contents have been fully administered to the patient by fully depressing the plunger. Manage this syringe as solid waste.

### Residues in other containers and "non-empty" dispensing and unit-dose containers

Some containers cannot be emptied using normal means. Examples of "non-empty" containers include:

- Residue in intravenous (IV) bags and tubing.
- Residue in syringes when the plunger wasn't fully depressed.
- Residue in inhalers, aerosols, and nebulizers.
- Residue in tubes of ointment, gels, or creams.
- Dispensing bottles, vials, or ampules exceeding one liter or one thousand pills.

These containers are not "empty" and cannot be managed as solid waste. Non-empty containers must be managed as dangerous waste under the dangerous waste regulations.

### Residues from containers of chemotherapy agents

If you do not identify and segregate the containers that held RCRA chemotherapy waste (P- or U- listed or characteristic), you must manage all chemotherapy containers as dangerous waste. Ecology recommends managing all empty chemotherapy containers, regardless of size, as dangerous waste pharmaceuticals under this policy.

## Can I still use a reverse distributor under this policy?

Except for DEA controlled substances, you can only use a reverse distributor under this policy for "creditable pharmaceuticals." Creditable pharmaceuticals are those that "*can be used for its intended purpose or returned to a manufacturer, wholesaler, or reverse distributor for credit*…"

Pharmaceuticals that can still be used for its intended purpose and be credited may be sent to a reverse distributor. You should follow the manufacturer's or reverse distributor's handling guidelines to ensure receiving credit. Maintain copies of your reverse distribution inventory records or invoices that show the credit assigned.

Pharmaceuticals that cannot be used or sold for its intended purpose and/or be returned for credit, may not be sent to a reverse distributor because it is inherently "waste-like." Non-creditable pharmaceuticals must be managed as pharmaceutical waste under this policy or under the Dangerous Waste Regulations.

Remember to review inventory reports to verify that an item sent to a reverse distributor was given a credit. Items not credited should be considered non-creditable in the future until you have documentation to support the change in status. If a pharmaceutical that previously was "non-creditable" can now be returned for credit, it is now a "creditable" pharmaceutical. You should maintain communication records with your manufacturer or reverse distributor to support this change in status.

## What other regulations apply if I use this policy?

At a minimum, all facilities are subject to the following sections of the Dangerous Waste Regulations:

- WAC 173-303-050: Department of Ecology cleanup authority.
- WAC 173-303-145: Spills and discharges into the environment.
- WAC 173-303-960: Special powers and authorities of the department.

Transporters of dangerous waste pharmaceuticals must:
Maintain a current RCRA ID number as a hazardous waste transporter where applicable.
Meet all the dangerous waste transporter requirements under WAC 173-303-240.
Meet all DOT transportation requirements for shipping hazardous materials and waste, including 49 CFR and WAC 173-303-190.

Transporters of creditable and non-creditable pharmaceuticals must also maintain all necessary licenses with the Board of Pharmacy and/or DEA for the handling of pharmaceuticals.

## What are the export and donation requirements?

All pharmaceutical waste exports must comply with EPA export requirements under 40 CFR Part 262 Subparts E & H. Records of the pharmaceutical export must be kept on site and are subject to inspection.

Ecology encourages facilities to follow the World Health Organization's (WHO) Guidelines for Drug Donation.[1] The WHO's core principles ask donors to ensure that pharmaceutical donations:

- Are of maximum benefit to the recipient.
- Respect the wishes and authority of the recipient.
- Strictly avoid any double standards in quality.
- Are based on effective communication between donor and recipient.

[1] http://www.who.int/selection_medicines/emergencies/guidelines_medicine_donations/en/

## Definition of terms used in this policy

The following terms are used in this policy and have specific meanings. Some of these terms are defined in the dangerous waste regulations and others were written to help provide clarity about this policy. If in doubt, refer to the regulatory definitions in WAC 173-303-040.

### State-only Conditional Exclusion

Pharmaceuticals that designate as state-only dangerous waste and not a RCRA waste are eligible for management under the Conditional Exclusion, WAC 173-303-071(3)(nn).

If managed as prescribed in the exclusion, state-only pharmaceutical waste does not need to be counted towards generator status and does not need to be reported annually. The Conditional Exclusion requires the incineration of state-only pharmaceutical waste at either:

i. A facility permitted to incinerate municipal solid waste; or
ii. A controlled combustion unit with:
    (A.) Heat input greater than 250 million British Thermal Units (BTUs) per hour.
    (B.) Combustion zone temperatures greater than 1500 degrees Fahrenheit.

The Conditional Exclusion does not apply to any RCRA hazardous pharmaceutical waste. It is intended for finished drug products only, not ingredients. It allows for the simple accumulation of waste and not to be used to treat dangerous waste.

### Creditable pharmaceutical

A pharmaceutical that can be used for its intended purpose or returned to a manufacturer, wholesaler, or reverse distributor for credit is creditable. Creditable pharmaceuticals are not subject to the Dangerous Waste Regulations since they are considered product-like until credit is given. Any pharmaceutical disposed without credit is considered non-creditable in the future until there is a documented change in credit status by the reverse distributor.

### Dangerous waste

Any waste that designates under WAC 173-303-070(3). Dangerous waste includes both RCRA hazardous waste and state-only dangerous waste.

### Dangerous waste pharmaceutical

Any pharmaceutical, as defined by RCW 69.04.009, that designates as a dangerous waste.

### Dual waste

Dangerous waste pharmaceuticals that are also infectious or potentially infectious. Examples include, non-empty syringes containing dangerous waste pharmaceuticals with needles attached.

**Non-creditable pharmaceuticals**
A pharmaceutical that cannot be used for its intended purpose, sold, or returned to the manufacturer, wholesaler, or reverse distributor for credit. This may include, but is not limited to:

- Expired pharmaceuticals
- Outdated items repackaged at the pharmacy
- Partial IVs, ampules, syringes, ointments, creams, lotions, and inhalers
- Dropped pills
- Patient medications left at the hospital
- Samples

**P-listed hazardous waste**
Any commercial chemical product in which the listed chemical is the sole active ingredient. Pharmaceuticals are commercial chemical products. A commercial chemical product is a substance manufactured or formulated for commercial or manufacturing use, which consists of the commercially pure grade of the chemical, any technical grades of the chemical, and all formulations in which the chemical is the sole active ingredient.

**RCRA hazardous waste**
For the purpose of pharmaceutical waste, RCRA hazardous waste refers to any pharmaceuticals that designate as dangerous waste under WAC 173-303-080 through -090. RCRA hazardous wastes include lists of certain discarded chemical products, manufacturing/industrial processes, or wastes with hazardous characteristics of ignitability, corrosivity, reactivity, or toxicity.

**Reverse distribution**
The practice of shipping unwanted, creditable pharmaceutical products to a third party with the intent of receiving manufacturer credit.

**State-only dangerous waste**
Washington considers toxicity and persistence as criteria used to designate waste as dangerous in addition to the RCRA listing and characteristics. For the purpose of this policy, state-only dangerous waste refers to any pharmaceutical waste designating as dangerous waste under WAC 173-303-100 that is not a RCRA hazardous waste.

The Washington State Department of Ecology's Hazardous Waste and Toxics Reduction Program has many sources of additional information you might find helpful in implementing this policy at your facility:

- *Guide to Pharmaceutical Waste Generators in Washington State*, Ecology publication #07-04-025
- *Profile and Notification*, Ecology publication #07-04-026
- Ecology's Managing Pharmaceutical Waste website
- Washington State Pharmacy Quality Assurance Commission
- Washington State Utilities and Transportation Commission
- U.S. Drug Enforcement Administration
- U.S. Department of Transportation
- Practice Greenhealth (formerly Hospitals for a Healthy Environment – (H2E)


**Americans with Disabilities Act (ADA) accommodations**

To request ADA accommodation including materials in a format for the visually impaired, call the Hazardous Waste and Toxics Reduction Program, 360-407-6700. Persons with impaired hearing may call Washington Relay Service at 711. Persons with speech disability may call TTY at 877-833-6341.

*This document was formatted to meet accessibility standards on 06/20/2017.*
*The content remains the same.*