



Interim Enforcement Policy

Pharmaceutical Waste in Healthcare

The Washington State Department of Ecology (Ecology) is announcing an interim enforcement policy for pharmaceutical waste. Within its enforcement discretion, Ecology will refrain from enforcing portions of the *Dangerous Waste Regulations* [Chapter 173-303 Washington Administrative Code (WAC)] at facilities meeting the conditions of this policy.

Eligible facilities may use this policy to manage all pharmaceuticals, as defined by RCW 69.04.009, that are (1) non-viable or (2) discarded for any reason. Facilities may not use this policy for non-pharmaceutical waste, radioactive pharmaceutical waste, or anesthesia gases.

This is not a new rule. This policy provides an option to the existing rules for managing pharmaceutical waste. Any pharmaceutical waste not managed according to this policy is subject to full regulation under the *Dangerous Waste Regulations*.

Why do we need this policy?

The presence of pharmaceuticals in the environment is a worldwide concern. Recent studies identified pharmaceutical contaminants in the waterways of thirty US states, including Washington¹. Current wastewater treatment technology does not remove all pharmaceuticals. Using the sewer, regulated medical waste containers, or landfill to dispose of pharmaceutical waste contributes to the contamination of groundwater, surface water, and drinking water. The size of this waste stream will continue to grow due to the increased use of pharmaceuticals.

Many waste pharmaceuticals designate as either federal [Resource Conservation and Recovery Act (RCRA), WAC 173-303-080 and -090] hazardous waste or Washington state-only dangerous waste [WAC 173-303-100]. In this document, dangerous waste includes both RCRA hazardous waste and state-only dangerous waste unless otherwise specified.

It can be difficult to manage pharmaceutical waste in compliance with the *Dangerous Waste Regulations* and the regulations of other agencies. The goals of this policy are to (1) protect human health and the environment, (2) simplify compliant pharmaceutical waste management, and (3) clarify compliance standards.

The US Environmental Protection Agency (EPA) and other states are in the process of considering options for how to best manage pharmaceutical waste. This policy will remain in effect until Ecology addresses this waste stream through rule making or modifies this policy.

Who can use this policy?

Eligible facilities include:

- **Patient care facilities.** Hospitals, acute care facilities, outpatient surgery centers, practitioner offices, clinics, dental offices, nursing units, ambulatory clinics, and veterinary care facilities.
- **Retail pharmacies.** Businesses that dispense pharmaceuticals to the consumer.

Interim Enforcement Policy: Pharmaceutical Waste in Healthcare

Ineligible facilities 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 viable pharmaceuticals for credit.
- **Research laboratories.**

What are the benefits of following this policy?

Facilities that manage pharmaceutical waste according to the requirements of this policy receive the following benefits:

- Use of a representative profile of the pharmaceutical waste (three month minimum) instead of continuously designating under WAC 173-303-070(3).
- Accumulation of pharmaceutical waste for up to 180 days.
- Quantity Exclusion Limits do not apply to pharmaceutical waste.
- Pharmaceutical waste does not count toward generator status.
- Pharmaceutical waste does not have to be reported on the Dangerous Waste Annual Report.

What are the generator requirements?

Profile Your Waste. Complete a pharmaceutical waste profile by determining:

- The waste codes that apply to pharmaceutical waste at your facility.
- A representative percentage range by weight for each waste pharmaceutical. You can do this by using generator knowledge.

For example:

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%
P042*	Epinephrine, including containers	5%	15%
P075	Nicotine, including containers	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	7%	65%

**Note: Washington State Department of Ecology considers salts of epinephrine, including epinephrine hydrochloride, epinephrine borate, and epinephrine bitartrate to also be P042 waste since the epinephrine is still the sole-active ingredient. The salt acts primarily as a carrier by facilitating solution of the epinephrine. It is not an active ingredient. Epinephrine products in combination with other drugs, like lidocaine, are not P042 since lidocaine is also an active ingredient.*

Interim Enforcement Policy: Pharmaceutical Waste in Healthcare

Send your initial profile to Ecology with your notification (see the **Notify Ecology** section below). Update your waste profile at least every three years or whenever significant changes are made to your facility's operations. Do not send updated profiles to Ecology. Current pharmaceutical waste profiles must be kept on-site and are subject to inspection. For additional information refer to Ecology publication #07-04-026, *Profiling and Notification Fact Sheet*.

Notify Ecology. Send notification to Ecology at the address below, indicating that your facility is managing pharmaceutical waste under this policy. The notification must be signed by the pharmacy manager and the environmental manager. Include a copy of your completed profile(s).

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

Train Your Staff. All staff involved in pharmaceutical waste management must be trained. Training must cover appropriate safety and emergency procedures, proper waste management, and recordkeeping.

Accumulate Waste. Accumulate pharmaceutical waste in a manner that reduces accidental releases and provides reasonable protection for safety, security, and the environment. You must:

- Place absorbent material in the bottom of containers storing liquid waste.
- Use containers compatible with their contents.
- Do not mix or store incompatible wastes in the same container.
- Keep accumulation containers closed unless adding or removing waste.
- Keep spill cleanup materials and personal protective equipment on-site.
- Label containers with the words “Non-Viable Hazardous Pharmaceutical Waste.”
- Label containers with all appropriate risk labels such as “Ignitable”, “Corrosive”, or “Toxic.”
- Label containers with an accumulation start date. The start date begins when the first item is placed in the container.
- Limit accumulation to 180 days. No quantity limits apply to the accumulation of pharmaceutical waste prior to transportation. Check with your local fire marshal for regulations that may apply to your accumulation area.
- Segregate and package pharmaceutical waste according to the U.S. Department of Transportation (DOT) regulations for shipment.

Dispose of Waste Properly. Manage all pharmaceutical waste according to this policy or the *Dangerous Waste Regulations*. Pharmaceutical waste managed under this policy must be incinerated at a RCRA permitted incinerator. Your facility can choose to separate RCRA waste from state-only pharmaceutical waste. State-only pharmaceutical waste may be incinerated according to this policy or the conditional exclusion [WAC 173-303-071(3)(nn)].

- Under this policy, pharmaceutical waste must be:
 - Sent to a RCRA permitted incinerator on a Hazardous Waste Uniform Manifest regardless of generator status.
 - State-only pharmaceutical waste may be segregated and managed under the conditional exclusion [WAC 173-303-071(3)(nn)].

Interim Enforcement Policy: Pharmaceutical Waste in Healthcare

- Under the *Dangerous Waste Regulations*, pharmaceutical waste must be:
 - Sent to a RCRA permitted incinerator on a Hazardous Waste Uniform 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 may be sent segregated and managed under the conditional exclusion [WAC 173-303-071(3)(nn)].
 - Counted and reported annually as described in WAC 173-303-060(5).
 - Accumulated on-site as prescribed in WAC 173-303-170(3)(a) based on generator status.

- Manage dangerous waste which is also infectious, “dual waste”, under the *Dangerous Waste Regulations* or this policy.
 - Send dual waste designating as dangerous waste to a RCRA permitted facility also permitted to accept infectious materials.
 - Send dual waste designating as state-only dangerous waste to an incinerator meeting the requirements of the conditional exclusion [WAC 173-303-071(3)(nn)] and permitted to accept infectious materials.
 - Transport dual waste following DOT requirements for hazardous and infectious materials.

- Only the following pharmaceutical wastes are eligible for sewer disposal with written approval from your local wastewater discharge and permit authority:
 - Saline, dextrose and sterile water solutions without vitamins or other additives.
 - Partially administered doses of controlled substances wasted by witnessed destruction in patient care areas only. *Note: Unused controlled substances from patient-care areas should be sent back to the pharmacy whenever possible (see Use the Reverse Distribution System section below).*

- Empty Containers.** Containers that held pharmaceuticals may be dangerous waste. Containers include but are not limited to:
 - Syringes
 - Vials
 - IV bags and tubing
 - Ampoules

- Under this policy, an “empty” container may be considered solid waste. A container is “empty” when it meets all the following criteria:
 - All commonly used practices for emptying the type of container have been applied, and
 - The remaining waste is 3% or less of the capacity of the container, and
 - Containers from a pharmaceutical whose sole active ingredient is listed under WAC 173-303-9903 for “P” wastes have been triple-rinsed.
 - Some examples of when an empty container is solid waste:
 - A fully administered IV bag that contained nitroglycerin is not a listed waste since the medicinal formulation of nitroglycerin is not P-listed. The empty IV bag can be considered solid waste.
 - Mitomycin C is a dangerous waste but not a P-listed waste. If the drug is fully administered to the patient and remaining residue is less than 3% of the capacity of the IV bag, it is solid waste.
 - A syringe that contained morphine is considered “empty” when the contents have been fully administered to the patient by fully depressing the plunger. You can manage this “empty” syringe in an appropriate sharps container.

Interim Enforcement Policy: Pharmaceutical Waste in Healthcare

- You must manage the following containers as dangerous waste:
 - Containers not meeting all the “empty” criteria listed above.
 - Containers from chemotherapy agents.
 - Unless you identify and segregate P-listed chemotherapy containers, all chemotherapy containers must be managed as dangerous waste.
 - Some examples of when a container is dangerous waste:
 - A vial, syringe, or IV bag that contained epinephrine or epinephrine hydrochloride is still a P042 listed waste, regardless of how much remains in the vial, since it is not practical or safe to triple-rinse the vial.
 - A vial, syringe or IV bag that held arsenic trioxide is a P012 listed waste, regardless of how much remains in the bag, since it is not practical to triple-rinse the bag.

Use the Reverse Distribution System. The following materials are eligible for reverse distribution:

- Viable pharmaceuticals. (See definitions)
- Waste controlled substances. Both viable and non-viable controlled substances can be sent to a Drug Enforcement Administration (DEA) licensed reverse distributor. You must ensure that:
 - Any controlled substances that designate as a RCRA hazardous waste are sent to a RCRA permitted incinerator.
 - The remaining controlled substances must be incinerated at a facility meeting the requirements of the conditional exclusion.

Non-viable pharmaceuticals, that are not controlled substances, must be managed as pharmaceutical waste under this policy or the *Dangerous Waste Regulations*. To determine whether a pharmaceutical is viable:

- **Check the definition of non-viable.** If a pharmaceutical cannot be used for its intended purpose, sold or returned for credit, and cannot be sent to the reverse distributor it is inherently “waste-like”.
- **Contact your reverse distributor.** If a pharmaceutical can be credited, it may be sent to the reverse distributor. Follow the manufacturer’s or reverse distributor’s handling guidelines to ensure credit.
- **Check your inventory reports.** Review inventory reports to verify that an item was given a credit. Items not credited should be considered non-viable in the future unless you have documentation to support the change in status.

Note: If a pharmaceutical that previously was non-viable can be returned for credit, it is now a viable pharmaceutical. You should maintain communication records with your manufacturer or reverse distributor to support this change in status.

Consistently sending non-viable pharmaceuticals to a reverse distributor is a violation of the *Dangerous Waste Regulations* and this policy unless:

- Transportation and final disposal comply with requirements of the *Dangerous Waste Regulations* or this policy, and
- The reverse distributor has a RCRA Treatment, Storage or Disposal Facility (TSDF) Permit or complies with the transfer facility requirements of WAC 173-303-240(6).

Keep Records. The following records must be available for inspection on-site for five years:

- Pharmaceutical waste profile.
- Uniform Hazardous Waste Manifests.

Interim Enforcement Policy: Pharmaceutical Waste in Healthcare

- Reverse distributor inventory reports.
- 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.
- ☑ **Other Applicable Regulations.** 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.

What are the transporter requirements?

Transporters of dangerous waste pharmaceuticals must:

- Maintain a current RCRA ID number as a Hazardous Waste Transporter.
- 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 viable and non-viable pharmaceuticals must also maintain all necessary licenses with the BOP 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 Code of Federal Regulations* (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* [<http://www.who.int/inf-pr-1999/en/pr99-45.html>]. 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 Kolpin, D.W., Furlong, E.T., Meyer, M.T., Thurman, E.M., Zaugg, S.D., Barber, L.B., and Buxton, H.T., 2002, *Pharmaceuticals, hormones, and other organic wastewater contaminants in U.S. streams, 1999-2000--A national reconnaissance*: Environmental Science and Technology, v. 36, no. 6, p. 1202-1211.

Johnson, A., Carey, B., and Golding, S., November 2004, *Results of a Screening Analysis for Pharmaceuticals in Wastewater Treatment Plant Effluents, Wells, and Creeks in the Sequim-Dungeness Area*: Environmental Assessment Program, Washington State Department of Ecology, Publication Number 04-03-051.

Interim Enforcement Policy: Pharmaceutical Waste in Healthcare

Definitions

The following terms are for the purpose of the *Interim Enforcement Policy for Pharmaceutical Waste in Healthcare* only. Some of the terms are defined in the *Dangerous Waste Regulations* and others were written to provide clarity for pharmaceutical waste managed under this policy.

Conditional exclusion [WAC 173-303-071(nn)]. Pharmaceutical that designates as state-only dangerous waste and not a RCRA waste is eligible for management under the conditional exclusion to the *Dangerous Waste Regulations*.

If managed as prescribed in the exclusion, the 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 per hour (BTUs/hr), and
 - (B) combustion zone temperatures greater than 1500 °F.

The conditional exclusion does not apply to any RCRA hazardous pharmaceutical waste.

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

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

P-listed hazardous waste. Any commercial chemical products 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.

Non-viable pharmaceutical. 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.
- Dropped pills.
- Partial IVs, ampoules, ointments, creams, lotions and inhalers.
- Patient medications left at the hospital.
- Samples.

RCRA hazardous waste. For the purposes 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, viable 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.

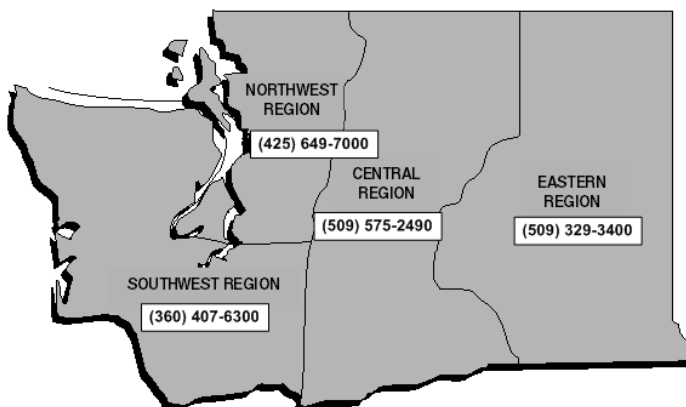
Viable pharmaceutical. A pharmaceutical that can be used for its intended purpose or returned to a manufacturer, wholesaler, or reverse distributor for credit is viable. Viable pharmaceuticals are not subject to the *Dangerous Waste Regulations* since they are considered product-like. Any pharmaceutical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

Interim Enforcement Policy: Pharmaceutical Waste in Healthcare

Additional Resources

- Washington State Department of Ecology Hazardous Waste and Toxics Reduction Program:
 - Additional guidance to the *Interim Enforcement Policy for Pharmaceutical Waste in Healthcare*
 - Ecology Publication #07-04-025, *Quick Guide to Pharmaceutical Waste Management*
 - Ecology Publication #07-04-026, *Profile and Notification*
 - Managing Pharmaceutical Waste Web site:
<http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/index.html>
 - Regulatory Information & Assistance:
http://www.ecy.wa.gov/programs/hwtr/reg_comp_guide/index.html
 - Hazardous Waste Service Provider: <http://www.ecy.wa.gov/apps/hwtr/hwsd/default.htm>
- Washington State Board of Pharmacy Web site:
<https://fortress.wa.gov/doh/hpqa1/HPS4/Pharmacy/default.htm>
- Washington State Utilities and Transportation Commission: <http://www.wutc.wa.gov/>
- US Drug Enforcement Administration: <http://www.deadiversion.usdoj.gov/>
- US Department of Transportation: <http://www.dot.gov/>
- Practice Greenhealth (formerly Hospitals for a Healthy Environment - H2E)
 - <http://www.practicegreenhealth.org>
 - Managing Pharmaceutical Waste – a 10-step Blueprint: <http://cms.h2e-online.org/ee/hazmat/hazmatconcern/pharma/>
- Maryadele J. O’Neil, Patricia E. Heckeman, Cherie B. Koch, Kristin J. Roman, Catherine M. Kenny (2006). “*The Merck Index* (14th ed.). Whitehouse Station, NJ: Merck Research Laboratories, a Division of Merck & Co., Inc. PDF of the title page: http://www.merckbooks.com/mindex/pdf/title_page_14.pdf

If you need more information contact your nearest Ecology regional office:



If you need this information in an alternate format, please call the Hazardous Waste and Toxics Reduction Program at 360-407-6700. Persons with hearing loss can call 711 for Washington Relay Service. Persons with a speech disability can call 877-833-6341.