Fact Sheet For Hazardous Waste Pharmaceuticals

The New Mexico Environment Department (NMED) provides this Hazardous Waste Pharmaceutical Guidance to assist NM's regulated community to remain compliant when both managing hazardous waste pharmaceuticals and determining when a pharmaceutical becomes a hazardous waste. Please note that this guidance is provided only to address frequently encountered concerns and does not address all applicable regulatory requirements associated with pharmaceuticals.

Managing Hazardous Waste Pharmaceuticals

Basics - Pharmaceuticals (e.g., drugs, medications) may be either a "listed" hazardous waste as listed at 40 CFR Part 261 Subpart D (discussed in detail below), or include ingredients in such concentrations that may cause the pharmaceutical to be a "characteristic" hazardous waste (characteristics include toxicity, ignitability or corrosivity) as specified at 40 CFR Part 261 Subpart C.

Do not pour or dispose of any pharmaceuticals down the drain or the toilet.

Bio-hazardous Medical Waste (infectious waste, red bag waste) – Hazardous waste pharmaceuticals that are contaminated with an infectious waste must be managed at a minimum as a hazardous waste. Store all hazardous wastes in a separate, labeled container and not in a bio-hazardous medical waste red container. Label hazardous waste pharmaceutical containers as "hazardous waste".

Reverse Distribution - NMED does not recognize the reverse distribution of expired hazardous waste pharmaceuticals. Once a product has expired it is considered a waste and must be disposed of in accordance with hazardous waste regulations. Disposal costs can be minimized by monitoring pharmaceutical inventory and only keeping as much drug/chemical on site as is needed, or reverse distributing pharmaceuticals prior to their expiration date.

Transportation - A container of hazardous waste pharmaceuticals must be picked up and transported by a hazardous waste transporter who has notified NMED about their transporting activities (Fedex is not a hazardous waste transporter). Maintain a copy of the manifest received from the transporter on-site for 3 years to demonstrate proper disposal and to demonstrate the amounts of hazardous pharmaceuticals generated. Waste management companies can assist you with the preparation of your manifests.

Special Considerations for Listed Hazardous Waste Pharmaceuticals

P and U listed pharmaceuticals - Certain drugs are regulated under RCRA as acutely hazardous waste ("P-listed") or as toxic hazardous waste ("U-listed") in 40 CFR § 261.33. To be in compliance, a facility must dispose of unused preparations as hazardous waste.

Mixtures of Listed Chemicals and Other Medications – As long as the listed pharmaceutical chemical is the sole active ingredient of a mixture of medications, the mixture is a listed hazardous waste (e.g., arsenic trioxide and saline solution).

Spills of a Listed Hazardous Waste Pharmaceuticals - Residues from a spill of unused preparations of P or U-listed waste must be managed as hazardous waste.

Generator Status - Assuming that no other hazardous wastes are generated, a facility that generates less than 2.2 pounds (1 kilogram) of acutely hazardous waste in any calendar month is categorized as a Conditionally Exempt Small Quantity Generator (CESQG). Once this maximum amount is exceeded, the facility would be considered a Large Quantity Generator and subjected to additional regulations. The CESQG limit for non-acute hazardous waste is 220 pounds (100 kilograms). A generator log should be kept of the p-listed waste generated. The log should clearly notate the amount or the quantity of waste and when the waste was last picked up.

RCRA-empty - Empty P-list hazardous waste pharmaceutical containers must be triple rinsed (and the rinsate managed as hazardous waste) to be considered RCRA-empty or managed as a hazardous waste. P-listed waste containers include, but are not limited to, empty vials, bottles, and containers. Blister packs and wrappers can go into the trash. Only empty syringes used to administer the drug can go into the bio-hazardous medical waste red container. Empty U-listed hazardous pharmaceutical containers are considered RCRA-empty.

Most Common Listed Hazardous Wastes Pharmaceuticals

RCRA "Listed Hazardous Waste" that *may* be found in Medical Practices (not all of the chemicals/drugs listed below are used in all practices):

P-Listed hazardous wastes (acutely hazardous):

Chemical (drug)	Waste Code
Arsenic trioxide	P012
Nicotine	P075
Physostigmine	P204
Physostigmine salicylate	P188
Warfarin >0.3%	P001

U-Listed hazardous wastes (toxic):

Chemical (drug)	Waste Code	Chemical (drug)	Waste Code
Chloral hydrate	U034	Saccharin	U202
Chlorambucil	U035	Paraldehyde	U182
Cyclophosphamide	U058	Phenol	U188
Daunomycin	U059	Reserpine	U200
Dichlorodifluoromethane	U075	Resorcinol	U201
Diethylstilbestrol	U089	Selenium sulfide	U205
Hexachlorophene	U132	Streptozotocin	U206
Lindane	U129	Trichloromonofluromethane	U121
Melphalan	U150	Uracil mustard	U237
Mitomycin C	U010	Warfarin <0.3%	U248

NOTE: This is not a complete list of all chemicals/drugs that may be hazardous waste

NMED recommends managing all chemotherapy drugs as toxic hazardous waste because of the similarity in structure, mode of action and toxicity.

Unique Hazardous Waste Pharmaceuticals

Epinephrine - EPA Waste No. P042

EPA published a regulatory interpretation memo October 15, 2007 concluding that the listing description for epinephrine does not include salts. Epinephrine HCL and epinephrine bitarterate, the medically active forms of epinephrine in common use, are salts; therefore, expired or damaged medications, including used syringes such as Epi-Pens, that contain epinephrine or epinephrine residues as the sole active ingredient no longer have to be managed as hazardous waste when discarded. This includes lidocaine preparations containing epinephrine.

Nicotine - EPA Waste No. P075

Nicotine is listed as an acutely hazardous waste in 40 CFR § 261.33. Used nicotine patches and gum are not hazardous waste because the listing description applies only to unused commercial chemical products and spill residues. Unused nicotine patches and gum are hazardous waste if discarded.

Nitroglycerine - EPA Waste No. P081

NMED has adopted EPA's revisions to Part 261 that exempts waste nitroglycerine formulations that are not explosive from regulation as hazardous waste.

Warfarin/Coumadin - EPA Waste Nos. P001 (or U248 if less than 0.3%)

In general, when unused and discarded, warfarin is P001, an acute listed hazardous waste. However, where the amount of warfarin in the waste is present at concentrations of 0.3% or less, the hazardous waste listing is U248. Laboratory data has indicated that the amount of residue remaining in containers which formerly held Coumadin (warfarin) pills ranges from 0.0033 to 0.0039%, compared with the initial amount of warfarin in the container. By extrapolation, the results are applicable to bottles that formerly contained at least 50 coated tablets or capsules of Coumadin at a dosage of 10 milligram (mg), and bottles that formerly contained at least 110 coated tablets or capsules at a dosage of 1 mg. Therefore, containers which formerly held these two combinations of amounts and dosages are identified as U248 rather than P001. In that case, the containers would be "RCRA-empty" if all Coumadin pills have been removed. Triple rinsing is not required. "RCRA-empty" containers are not regulated as hazardous waste.

A generator of containers that formerly contained any other dosage/quantity combination of Coumadin pills, or that formerly contained liquid formulations or powders, may design and implement a laboratory study to demonstrate that the residues are < 0.3% of the initial amount of warfarin in the container. Until such demonstration is made, containers that held other dosage/quantity combinations, or that held liquid or powder formulations, must be disposed of as P001 hazardous waste or triple rinsed in accordance with 40 CFR 261.7 to render them "RCRA empty" and no longer hazardous waste.

Phenol - EPA Waste No. U188

Some over-the-counter medications, such as Chloraseptic, have phenol as the sole active ingredient. These are listed hazardous waste when unused packages are discarded rather than used. Phenol is the sole active ingredient, but is diluted with a carrier. Carriers, buffers, preservatives and fragrances or flavors in these products are not included for a functional property, and may be present in preparations without affecting their hazardous waste listing.

Hexachlorophene - EPA Waste No. U132

Commercial cleaning preparations containing hexachlorophene, such as pHisoderm or pHisoHex, do not meet the listing description for technical grade Hexachlorophene. Hexachlorophene is the main active ingredient, but in these preparations is formulated with detergents and emulsifiers which are included for their functional cleaning properties, so hexachlorophene is not the sole active ingredient and these cleaning preparations are not a hazardous waste.

Chromium or Selenium supplements - EPA Waste Nos. D007 and D010

Waste liquids that have more than 5 milligrams per liter (mg/l) chromium or 1 mg/l selenium are hazardous wastes because they exhibit the toxicity characteristic under 40 CFR 261.24. Solids that contain these metals are also regulated if they leach these concentrations when tested by the toxicity characteristic leaching procedure (TCLP) specified in this rule. For soluble metals, 100 mg/kg chromium and 20 mg/kg selenium will fail the test. For vials and tablets of unused materials, most will fail the TCLP test based on dose per weight of tablet or unit. Health care facilities must monitor the concentration of the metals in diluted medications in order to determine if these are regulated as hazardous waste when discarded.

Chromic Catgut Sutures - EPA Waste No. D007

Unused, discarded chromic catgut sutures should be presumed to be hazardous waste. Remnants and clippings generated during surgery can be disposed of as biomedical waste.

Insulin - potentially EPA Waste No. D024

Some insulin formulations contain m-cresol, and these are toxic hazardous wastes when m-cresol levels exceed 200 mg/l TCLP. It is permissible under hazardous waste regulations to crush the vials, handle the drained liquid as hazardous waste and manage the crushed glass as non-regulated material.

Phentermine – EPA Waste No. P046

Phentermine HCL is not listed. This was the same principle used for EPA's policy that epinephrine is listed as P042, but that the salts are not covered by the listing.

If you have questions related to hazardous waste pharmaceuticals or hazardous wastes, please call the New Mexico Environment Department's Hazardous Waste Bureau at 505-476-6000 or toll free at (866) 428-6535.