County of San Diego

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PHARMACEUTICAL WASTE

Hospitals, medical clinics, doctors, dentists, veterinarians, and other health care facilities generate several types of wastes. These include hazardous waste identified under the federal Resource Conservation and Recovery Act (RCRA), non-RCRA hazardous waste, and medical waste. When SB 1966 became effective in 1997, pharmaceutical wastes classified as non-RCRA (California only) hazardous waste were included under the definition of ***Medical Waste*****.** These wastes must be handled and disposed of as medical waste according to the requirements of the California Medical Waste Management Act (MWMA), Sections 117690 (3), 117747, and 118222 (b), California Health and Safety Code.

Some common questions being asked by health care facilities are:

1. ***What is a pharmaceutical waste?***
2. ***What is reverse distribution?***
3. ***How do I know if the pharmaceutical waste is a RCRA hazardous waste?***
4. ***How do I know if the pharmaceutical waste is a medical waste?***
5. ***How do I dispose of controlled substances?***
6. ***Can I use a sequestration unit for disposal?***

It is important to note that **it is the responsibility of the waste generator to determine if the waste pharmaceutical is a hazardous waste or a medical waste.** This guidance document can help facilities with their determination if their waste pharmaceuticals must be managed as hazardous waste or medical waste.

If a pharmaceutical waste is a hazardous waste, it must be managed according to California Title 22 hazardous waste requirements. These include proper labeling and disposal within accumulation time limits by a registered hazardous waste transporter on a California Uniform Hazardous Waste Manifest.

If a pharmaceutical waste is a medical waste, it must be managed according to MWMA requirements. These requirements include the waste being labeled with the words "Incineration Only" and disposed of within one year on a waste tracking document.

1. *What is pharmaceutical waste?*

Before defining pharmaceutical waste, it is important to understand what a pharmaceutical is. The MWMA section 117747 defines **pharmaceutical** as *a prescription or over-the-counter human or veterinary drug not regulated pursuant to the Resource Conservation and Recovery Act (RCRA) or the Radiation Control Law*.

The MWMA section 117690 (a), (b)(3) defines **pharmaceutical waste** as a type of medical waste. It further indicates that it is a pharmaceutical, including chemotherapy waste that is a waste (as defined in HSC 25124). A pharmaceutical waste does not include pharmaceuticals being sent out to a reverse distributor.

Pharmaceutical waste is to be separated from other medical waste, placed in a container labeled with the words “HIGH HEAT” or “INCINERATION ONLY” and incinerated at a permitted medical waste treatment facility.

2. *What is reverse distribution?*

A *reverse distributor* as defined in section 4040.5 of the Business and Professions Code, "means every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or non-saleable dangerous drugs or dangerous devices."

Be advised: Per the Department of Toxic Substance Control (DTSC), pharmaceuticals, which are RCRA hazardous waste, cannot be sent to a reverse distributor unless that reverse distributor is permitted as a hazardous waste treatment, storage, disposal facility (TSDF) or is authorized to accept this waste. It is the responsibility of the waste generator to determine if the waste pharmaceutical is either a 1) a RCRA hazardous waste, 2) a pharmaceutical that can be returned for credit, or 3) a California medical waste (cannot be returned for credit).

3. *How do I know if the pharmaceutical waste is a RCRA hazardous waste?*

Title 22 of the California Code of Regulations (CCR), Section 66261.33 states that a discarded listed material which is manufactured or formulated for commercial use and which consists of a commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is a **sole active ingredient,** is a RCRA listed hazardous waste. Therefore, if a pharmaceutical has a sole active ingredient that is listed in either the P or U lists, it is a RCRA hazardous waste.

The National Institutes of Health states that of the 39 drugs most used (both on patients and experimentally in laboratories), the following are considered hazardous wastes: Cytoxin (U058), Daunomycin (U059); Melphalan (U150), Mytomycin C (U010), Streptozotocin (U206).

Examples of products with a sole active ingredient contained on the P or U list

LISTING	ACTIVE INGREDIENT	EXAMPLES
P042	Epinephrine	Injectables
P075*	Nicotine and Salts	*Excludes over the counter gum, patches, lozenges
U002	Acetone	Solvent, nail polish remover
U010	Mitomycin C	Antineoplastic, chemotherapy
U035	Chlorambucil	Antineoplastic, chemotherapy
U044	Chloroform	Solvent, anesthetic
U058	Cyclophosphamide	Antineoplastic, chemotherapy
U089	Diethylstilbestrol	Antineoplastic, chemotherapy
U122	Formaldehyde	Preservative, disinfectant
U129	Lindane	Lice control spray, shampoos
U132	Hexachlorophene	Cleansers
U150	Melphalan	Antineoplastic, chemotherapy
U182	Paraldehyde	Sedative, DEA controlled
U188	Phenol	Throat sprays, mouthwash
U200	Reserpine	Antihypertensive
U210	Resorcinol	Keratolytic
U202	Saccharin and salts	Artificial sweeteners
U237	Uracil Mustard	Antineoplastic, chemotherapy
U248/P001	Warfarin and Salts	Anticoagulant

A pharmaceutical waste can also be a RCRA hazardous waste if it exhibits any of the characteristics of the following characteristics: ignitability (66261.21), corrosivity (66261.22 (a)(1) or (2)), reactivity (66261.23), and/or toxicity (66261.24 (a)(1)).

LISTING	RCRA CHARACTERISTIC	EXAMPLES
D001	**IGNITABLE**	
	• Aqueous based liquid with >24 % alcohol • Non-aqueous liquid with flash point ≤ 140º F • Oxidizers • Ignitable compressed gases	• Injectables, cough syrup, tinctures • Solvents, non-aqueous injectables • Whiteners, bleach, peroxides, and/or isobutene
D002	**CORROSIVE**	
	• Aqueous with pH ≤ 2.0 or ≥ 12.5	• Acids, bases, depilatories, hydroxides
D003	**REACTIVE**	
	• Reacts violently with water • Generates toxic gases when mixed with water • Generates cyanide or sulfide bearing gases • Capable of explosive reaction if heated or under confinement • Normally unstable	• Aerosols are the most common D003 waste
D004 – D043	**TOXIC**	
	• Determined by the Toxicity Characteristic Leaching Procedure (TCLP)	• See table below

ELEMENT OF TOXICITY	TCLP	EXAMPLES OF PRODUCTS
D005 - Barium	100mg/L	Enemas, colorings
D007 - Chromium	5 mg/L	Vitamin/mineral supplements
D009 - Mercury	0.2 mg/L	Colorings, vaccines, preps, injectables nasal, hemorrhoidal, ophthalmic
D010 - Selenium	1 mg/L	Vitamin/mineral supplements, shampoo
D011 - Silver	5 mg/L	Creams, applicators
D013 - Lindane	0.4 mg/L	Creams, lotions, shampoo
D024 – m-Cresol	200 mg/L	Some insulin and other injectables

The California Department of Public Health (CDPH) has received numerous inquiries about whether to place pharmaceutical waste into a pharmaceutical waste container or a hazardous waste container. Some medical waste haulers are telling their customers to place all types of pharmaceutical waste into a hazardous waste container. This is not a practice that CDPH or HMD endorses because it goes directly against waste minimization rules for USEPA. CDPH highly recommends that California non-RCRA hazardous waste be managed separately from RCRA hazardous waste. Only pharmaceutical waste that falls under RCRA, as amended (42 USCA Sec. 6901 et seq.) should be disposed of into a hazardous waste container. All remaining pharmaceutical waste that does not fall under the definition of RCRA waste (i.e. CA non-RCRA) should be disposed of into a pharmaceutical waste container. More information on RCRA waste can be found at www.epa.gov.

4. *How do I know if the pharmaceutical waste is a medical waste?*

Any prescription or over-the-counter human or veterinary drug that is not sent to a reverse distributor for credit and is not a RCRA hazardous waste must be managed as a “pharmaceutical waste” under the California MWMA.

5. *How do I manage controlled substances?*

Pharmaceutical wastes classified by the DEA as “controlled substances” must be disposed of in compliance with DEA requirements and are not exempt from RCRA hazardous waste or medical waste requirements.

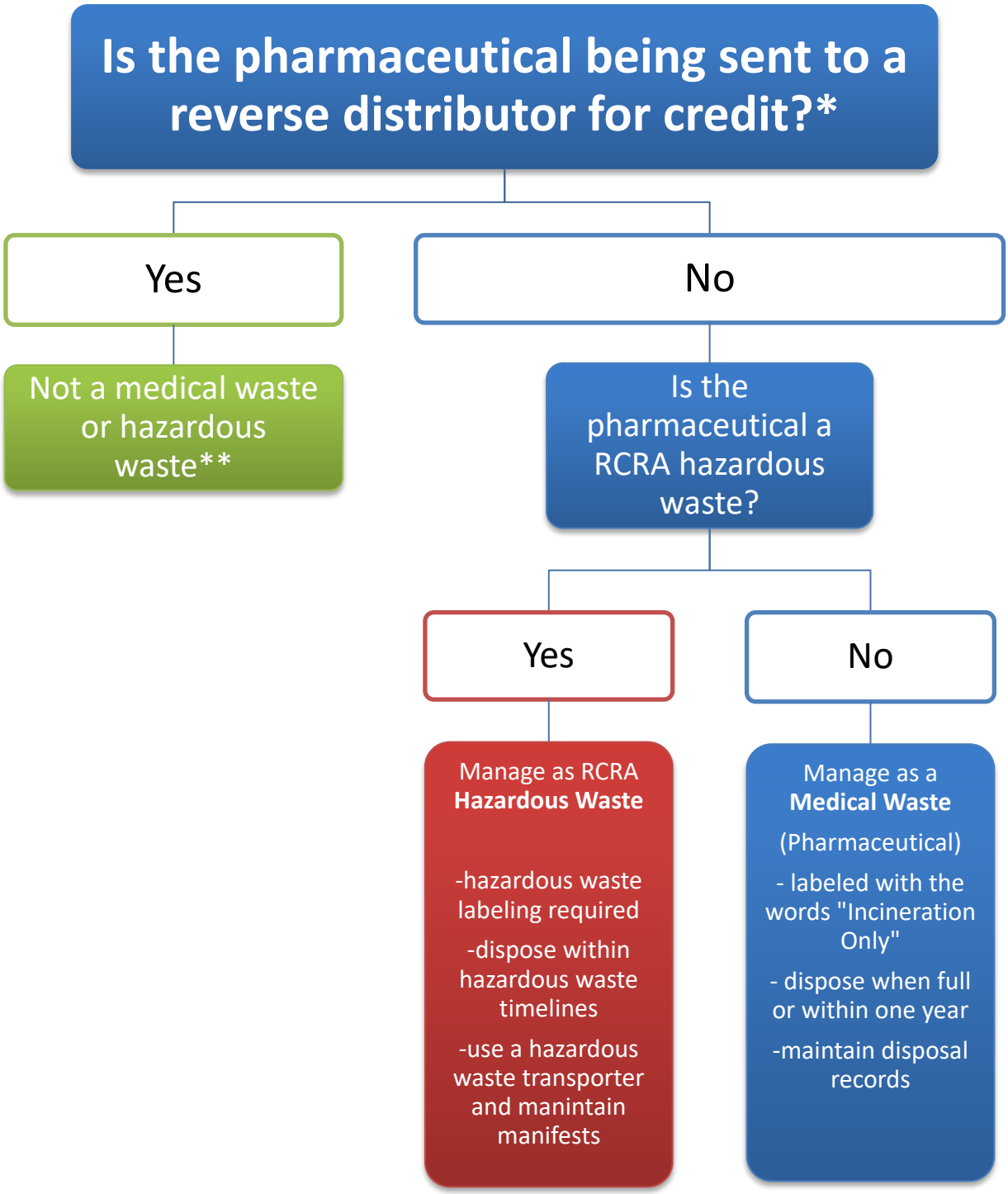
Under no circumstances should any waste medication – including controlled substance waste – be disposed of down the drain or into solid or biohazardous waste.

6. *Can I use a sequestration unit for disposal?*

Per the CDPH website: "Pharmaceutical waste generated in California must be treated by incineration, or by an alternative treatment technology that has received approval from (CDPH). The technologies on the CDPH's alternative medical waste treatment technologies list are the only alternative treatments approved for use in California. None of the charcoal-based products currently in use have gained this approval, so they must be disposed of in a pharmaceutical waste container. Do not place pharmaceuticals mixed with these products into the solid waste."

Be Advised: Pharmaceutical waste treated by unapproved treatment methods are still considered regulated medical waste and subject to all laws as defined in the MWMA.

Determining how to manage your pharmaceutical waste



* **Be advised:** hazardous waste and medical waste cannot be sent to a reverse distributor for waste determination and subsequent disposal.

****Important Note:** Facilities should be able to answer questions about pharmaceuticals being shipped offsite and pharmaceutical waste.

Pharmaceutical wastes that are subject to DEA and RCRA

TABLE 4—DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES PHARMACEUTICALS THAT ARE NOT IN COMMON USE

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Paraldehyde	1,3,5-Trioxane, 2,4,6-trimethyl-; Paral	Anticonvulsant	U182 toxic	IV	No longer in common use.
Paregoric	camphorated tincture of opium	Analgesic, expectorant, antidiarrheal.	D001 ignitable	III	No longer in common use.
Opium Tincture	Laudanam	Analgesic, antidiarrheal	D001 ignitable	II	No longer in common use.

TABLE 5—PHARMACEUTICALS THAT ARE DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES SALT(S) NO LONGER CONSIDERED HAZARDOUS WASTE

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Phentermine	alpha, alpha-Dimethylphenethyl amine; Benzeneethanamine, alpha,alpha-dimethyl-; Adipex-P, Atti Plex P, Fastin, Ionamin, Kraftobese, Panshape M, Obe-Nix, Pentercot, Phentride, Pro-Fast, Raphtre, Supramine, Tara-8, Termene, Termine, Zantryl.	Appetite suppressant.	P046, Acutely toxic	IV	If in salt form, it does not meet the P046 listing and medical dosage forms are salts.

TABLE 6—PHARMACEUTICALS STILL USED IN HEALTHCARE THAT ARE DEA CONTROLLED SUBSTANCES & RCRA HAZARDOUS WASTES

[Amendments in bold based on comments]

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Chloral; chloral hydrate.	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes.	Sedative	U034 toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics.
Fentanyl sublingual spray.	Subsys	Analgesic	D001 ignitable	II	Ignitable due to alcohol content.
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001 ignitable	IV	Ignitable due to alcohol content.
Testosterone gels/solutions.	Androgel, Axiron, Fortesta, Testim	Hormone	D001 ignitable	III	Ignitable due to alcohol content.
Valium injectable/gel	Diazepam, Diastat	Anti-anxiety	D001 ignitable	IV	Ignitable due to alcohol content.

https://www.govinfo.gov/content/pkg/FR-2019-02-22/pdf/2019-01298.pdf