

State of California—Health and Human Services Agency
Department of Health Services



California
Department of
Health Services

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To: Directors of Environmental Health
Medical Waste Program Managers

SUBJECT: MANAGEMENT OF PHARMACEUTICAL MEDICAL WASTE

During 1996, Senate Bill 1966 was signed into law. This bill redirected regulation of California only hazardous pharmaceutical waste from the California Department of Toxic Substances Control (DTSC) to the California Department of Health Services (DHS). This change in the law did not affect pharmaceutical waste characterized as hazardous waste or as solid waste; only those pharmaceuticals characterized as "California only hazardous waste." Although this change redirected the disposal of the California only portion of this waste stream, it did not change the method of classifying the waste, which remained with DTSC. The language of the bill has often been considered unclear and it is frequently misunderstood. Therefore compliance and enforcement of the handling of the "new medical waste" comprised of "California Only" pharmaceuticals have been mired in confusion. Characterizing the waste to determine whether it was medical waste, hazardous waste or solid waste has been at the core of the confusion.

The Pharmaceutical Waste Action Group was formed at the request of the California Association for Professionals in Infection Control (APIC) Coordinating Council (CACC) for the purpose of assisting the regulated community in understanding and complying with the Medical Waste Management Act (MWMA) as it relates to pharmaceuticals. Several meetings were held and a great amount of information was shared. DHS' goal in participating in these meetings has been to assist the group in understanding the law, properly classifying their waste, and disposing of this waste stream properly. While not all participants anticipated the same outcomes, it is believed that all parties have been assisted and a greater understanding of the law can be shared.

Highlighted below is information that resulted from the discussions held during the workgroup meetings. The information is listed in such a manner as to assist the regulated and regulatory communities in complying with and uniformly enforcing the law in an appropriate manner.

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- Pharmaceutical wastes may be medical waste, hazardous waste or solid waste. Proper classification is necessary to be in compliance with the laws regulating each waste type. Pharmaceutical wastes that must be managed according to the MWMA are those that are classified as "California only hazardous waste" by Chapter 11, Title 22, California Code of Regulations (22 CCR).
- According to 22 CCR, the generator of the waste is ultimately responsible for proper classification of waste streams. Once classified the generator is responsible to manage and dispose of the waste according to the rule governing the particular waste classification. The generator must demonstrate to the medical waste management enforcement agency that all pharmaceuticals that meet the criteria of California-only hazardous wastes are properly managed, stored, transported and treated per the MWMA.
- Generators of pharmaceutical medical waste must develop and implement a plan and procedure for properly managing and disposing of medical waste pharmaceuticals. Staff should be trained against an appropriate procedure. This plan must be included as part of the facility's Medical Waste Management Plan. The plan should be used as a tool to assist the facility in communicating, with the medical waste enforcement agency, the status of the facility's compliance with the MWMA
- Attached is a listing of commonly and routinely used pharmaceuticals characterized using the criteria outlined in Chapter 11, 22 CCR. This listing was developed by Kaiser Permanente-Baldwin Park and is being shared for the benefit of all. Use of this information should ease the burden of pharmaceutical characterization and enhance compliance with the MWMA. It is anticipated that pharmaceutical "user groups" will maintain this list and continue to test and characterize pharmaceuticals. DHS will make every attempt to stay abreast of all updates to the listing.
- The following are treatment options for the different categories of waste.
 - Solid Waste may be disposed of in the sewer or trash. Facilities need to coordinate and comply with disposal requirements of the local Privately Owned Treatment Works (POTW) and waste acceptance criteria of the municipal waste disposal facility.
 - Medical Waste (CA-only pharmaceuticals) must be treated through incineration.
 - Hazardous Waste (RCRA) must be managed and disposed of in accordance with 40 Code of Federal Regulations (CFR) 261 and Division 4.5, 22 California Code of Regulations (CCR).

**Pharmaceutical Toxicity Testing Results
Summarized as of 5/08/02**

Kaiser Toxicology testing, including Fish Toxicity testing

	Passed Fish-Toxicity (not CA-only Hazardous.) May be managed as Solid Waste (Public Resources Code § 40191)	Failed (CA-only hazardous.) Must be managed as Medical Waste (Health and Safety Code § 117635)	RCRA Hazardous Must be managed as Hazardous Waste
Not Tested; ¹			60% Barium Sulfate
Definitive ²	Amiodarone (900 mg/500 ml. D5W)	Propofol (1%)	
Screening ³	Ciprofloxacin (2 mg/ml in D5W)		
	Dexamethasone (10 mg/ml.)		
	Gentamicin (40 mg/ml.)		
	Metronidazole (5 mg/ml)		
	Milk of Magnesia		
	Mylanta (Kaiser Masanti)		
	Theophylline (200 mg/50 ml in D5W)		
	Oxytocin (40 units/liter in D5W)		
	Insulin (100 units/100 ml. NS)		
	Ceftriaxone (2 gm./50 ml.in D5W)		
	Norepinephrine (8 mg/250 ml. in D5W)		
	Doxycycline (100 mg/100 ml.in D5W)		
	Tobramycin (1200 mg/30 ml.)		
	Erythromycin (1 gm./200 ml. in NS)		
	Vancomycin (1 gm./200 ml. D5W)		
	Dobutamine (1 gm./250 ml. D5W)		
	Dopamine.HCl (1600 mcg./ml)		
	Magnesium Sulfate (40 mg./ml.)		
	Baxter Clinimix E Amino Acid/Electrolyte Soln		
	Epinephrine Injection (1 mg./10ml.)		
	Nitroglycerin (50 mg./250 ml. in D5W)		
	Heparin (50 units/ml.)		
	Lidocaine (2%).		

¹ Federally Hazardous by TCLP (toxicity characteristic leaching procedure)

² definitive test gives an actual LC50

³ screening test (Hazardous Waste Screening Bioassay) identifies whether the actual LC50 is below 400 mg/L (and definitely hazardous) or above 750 mg/L. and definitely non-hazardous