



# Managing Pharmaceutical Waste

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## Thanks to

Sharp Healthcare  
and our guest speakers

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## Today's Agenda

07:30 am — 08:00 am Registration & Refreshments  
 08:00 am — 08:15 am Introductions and Agenda  
 08:15 am — 09:00 am Pharmaceutical Waste Regulations (Michael Vizzier)  
 09:00 am — 09:30 am Proper Management of Non-Dispensable Pharmaceuticals (Timothy Fahy)  
 09:30 am — 09:45 am Break  
 09:45 am — 11:15 am Managing Pharmaceutical Waste (Charlotte A. Smith)  
 11:15 am — 11:45 am Non-RCRA Toxicity (Leon Wirschem)  
 11:45 am — 12:00 pm Closing remarks (Michael Vizzier)

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## Pharmaceutical Waste Regulations

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## Some of the Regulatory Agencies

<b>USEPA</b>	<b>CDPH</b>	<b>CUPA</b>
<b>OSHA</b>	<b>Pharmacy Board</b>	<b>Landfill</b>
<b>DEA</b>	<b>DTSC</b>	<b>Industrial Waste Water</b>

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## Pharmaceutical Waste Categories

- Controlled substance**
- RCRA hazardous waste**
- California medical waste**
- Solid waste**
- Recyclable material**
- Retrograde material**
- Surplus material**

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## Department of Environmental Health

- **Hazardous waste:** As the CUPA we work closely with DTSC to ensure consistent interpretation, implementation and enforcement.
- **Medical Waste:** As local implementing and enforcement Agency we work closely with CDPH to ensure consistent interpretation, implementation and enforcement.

**DEH's authority is limited to hazardous and medical waste.**

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## Hazardous Waste

- Resource Conservation and Recovery Act (RCRA)
  - Federal hazardous waste law.
  - Federal hazardous waste is called RCRA hazardous waste.
  - RCRA hazardous waste is regulated by US EPA, DTSC & the CUPA.
- Hazardous Waste Control Law
  - California hazardous waste law.
  - California hazardous waste is called non-RCRA hazardous waste.
  - Non-RCRA hazardous waste is regulated by DTSC & the CUPA.

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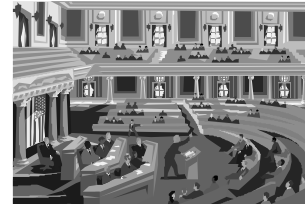
## Non-RCRA hazardous pharmaceutical waste = medical waste

- Hazardous Waste Control Law
  - California hazardous waste law.
  - California hazardous waste is called non-RCRA hazardous waste.
  - Non-RCRA hazardous waste is regulated by DTSC & the CUPA.
- In California, non-RCRA waste pharmaceuticals = medical waste pharmaceuticals.
- The next seven slides explain this conclusion.

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## SB 1966 of 1995



Senator  
Cathie Wright

- **Legislative analysis:** DTSC vs. DHS regulation. Current law classifies pharmaceutical waste as a hazardous waste rather than as a medical waste, thereby subjecting these generators to DTSC regulation. This bill reclassifies waste pharmaceuticals as "biohazardous waste" thereby making such waste subject to DHS regulation under the Medical Waste Management Act.

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## 117635. "Biohazardous waste" means any of the following:

- 117635 (g) Waste that is **hazardous** only because it is comprised of pharmaceuticals, as defined in Section 117747. Notwithstanding subdivision (a) of Section 117690, medical waste includes biohazardous waste that meets the conditions of this subdivision. Biohazardous waste that meets the conditions of this subdivision is not subject to Chapter 6.5 (commencing with Section 25100) of Division 20.

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## 117635 (g) Biohazardous waste means

- Waste that is **hazardous** only because it is comprised of pharmaceuticals, as defined in Section 117747.
- **Notwithstanding** subdivision (a) of Section 117690, medical waste includes biohazardous waste that meets the conditions of this subdivision.
- Biohazardous waste that meets the conditions of this subdivision is **not subject to Chapter 6.5** (commencing with Section 25100) of Division 20.

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## Section 117747

- "Pharmaceutical" means a prescription or over-the-counter human or veterinary drug.
- Pharmaceutical **does not include** any pharmaceutical that is **regulated under the:**
  - Resource Conservation and Recovery Act
  - Radiation Control Law

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## Notwithstanding §117690 & Not subject to Chapter 6.5 ?

- In California most categories of medical waste must meet a two pronged test in §117690:
  - Biohazardous or sharps waste **and**
  - Used in human or animal health care
- Notwithstanding subdivision (a) of Section 117690 means ignore the first "prong". It only has to be a hazardous pharmaceutical.
- Not subject to Chapter 6.5 means it's not regulated under California hazardous waste law.

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## What's hazardous Pharmaceutical?

Dear Mr. President Pro Tempore:

The purpose of this letter is to clarify the intent of Senate Bill 1966 which has already gone to Governor Wilson for signature.

SB 1966 redirects the regulation of that pharmaceutical waste which is currently regulated as California only hazardous waste from the California Department of Toxic Substances to the California Department of Health Services. Such waste is now not considered hazardous waste under Federal law nor as medical waste under California's Medical Waste Management Act (MWWA).

SB 1966 would not affect the regulation of that pharmaceutical waste which is currently not regulated as hazardous waste under California statute. Such pharmaceutical waste will continue to be regulated as solid waste pursuant to the California Integrated Waste Management Act.

Therefore, those facilities now accepting the pharmaceutical waste presently considered non-hazardous under California statute may continue to do so after the enactment of SB 1966 without modification.

Sincerely,

*Cathie Wright*  
CATHIE WRIGHT

## Medical Waste

- SB 1966 moved the regulation of hazardous waste pharmaceuticals that would be classified as a non-RCRA hazardous waste from DTSC to CDPH and reclassified it as medical waste.
- It did not change the regulatory status of solid waste pharmaceuticals.

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## Pharmaceutical Waste Management Standards

- RCRA hazardous waste pharmaceuticals
- Medical waste pharmaceuticals
- Retrograde, surplus pharmaceuticals

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## RCRA Hazardous Waste Pharmaceuticals

HAZARDOUS WASTE	
STATE & FEDERAL LAW PROHIBITS IMPROPER DISPOSAL IF FOUND, CONTACT THE NEAREST POLICE OR PUBLIC SAFETY AUTHORITY OR THE U.S. ENVIRONMENTAL PROTECTION AGENCY OR THE CALIFORNIA DEPARTMENT OF TOXIC SUBSTANCES CONTROL.	
PROPER D.O.T. SHIPPING NAME _____	UIC or NA# _____
GENERATOR INFORMATION: TELEPHONE _____	
NAME _____	
ADDRESS _____	
CITY _____ STATE _____ ZIP _____	
EPA I.D. NO. _____	MANIFEST DOCUMENT NO. _____
ACCUMULATION _____ CA _____ EPA _____	_____
CONTENTS, COMPOSITION: _____	
PHYSICAL STATE: HAZARDOUS PROPERTIES: <input type="checkbox"/> FLAMMABLE <input type="checkbox"/> TOXIC	
<input type="checkbox"/> SOLID <input type="checkbox"/> LIQUID <input type="checkbox"/> CORROSIVE <input type="checkbox"/> REACTIVITY <input type="checkbox"/> OTHER _____	
COMPLETE FOR STORAGE	HANDLE WITH CARE! CONTAINS HAZARDOUS OR TOXIC WASTES
COMPLETE FOR TRANSPORT	18

## RCRA Waste

- RCRA Hazardous Waste Pharmaceuticals
- Modified hazardous waste label



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## Medical Waste Pharmaceuticals


- Incinerate only - California law
- Generator information San Diego County Code
- Nothing else is required.

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## Medical Waste Pharmaceuticals

PHARMACY WASTE ONLY  
HANDLE WITH CARE  
PHARMACY WASTE - INCINERATE ONLY

**NO**   
**NO SHARPS!** **NO BLOOD!**

WASTE GENERATOR INFORMATION  
VA SAN DIEGO HEALTHCARE SYSTEM (OHS)  
3350 LA JOLLA VILLAGE DR.  
SAN DIEGO, CA. 92161  
Accumulation Start Date: \_\_\_\_\_ Phone: (858) 642-1052

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## RCRA Accumulation Time

- LQGs - 90 days.
- SQGs - 180\* days.
- Satellite accumulation time limit is one year (total).

\*SQGs can accumulate hazardous waste for 270 days if the destination facility is greater than 200 miles away.

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## Med waste pharmaceutical accumulation time

- A person may store pharmaceutical waste at an onsite location for not longer than 90 days when the container is ready for disposal or, unless prior written approval from the enforcement agency or the department is obtained.
- The container shall be emptied at least once per year, unless prior written approval from the enforcement agency of the department is obtained.

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## Retrograde (RCRA waste)

- Retrograde is a California term for commercial chemical products that are hazardous and cannot be used, sold or distributed for use in an originally intended or prescribed manner because:
  - has exceeded a specified or recommended shelf life;
  - it has undergone chemical, biochemical, physical or other changes due to the passage of time or the environmental conditions under which it was stored or
- Retrograde pharmaceuticals must go to a reverse distributor within one year.

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## Recyclable (RCRA)

- Recyclable typically means a waste that must be reclaimed before it can be reused
- For pharmaceuticals this is most likely a retrograde material that has **not** gone to a reverse distributor within one year after shelf-life expiration under the California scheme.
- It requires some additional management procedures.

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## Surplus

- "Surplus material" means an unused raw material or commercial product obtained by a person who intended to use or sell it, but who no longer needs it, and who transfers ownership of it to another person for use in a manner for which the material or product is commonly used. Surplus material is excess material. Surplus material is neither of the following:
  - a retrograde material as defined in this section;
  - a recyclable material as defined in this section.
- A surplus materials is not regulated as a hazardous waste but reverse distribution for pharmaceuticals is a logical option.

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## Solid Waste

- A non-hazardous waste pharmaceutical
  - Not a RCRA hazardous waste
  - Not a medical waste
- Likely subject to landfill or industrial waste water requirements.
- "No Drugs Down the Drain."

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## Pharmaceutical waste management will be explained in greater clarity and detail in the subsequent presentations.

These presentations will be posted on our website at:  
www.sdcdeh.org

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A to Z Services

E-mail Sign-up

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## A copy of Today's Presentations

Pharmaceutical Waste

January 20, 2010 Workshop Presentations:

- Pharmaceutical Waste Regulations
- Management of Non-Dispensable Pharmaceuticals
- Handling Pharmaceutical Waste
- Non-RCRA Toxicity

PHM Forms | PHM Publications | PHM Topics

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# Questions?

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