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# **Managing Pharmaceutical Waste**

## **A 10-Step Blueprint for Healthcare Facilities**

*Revised for California Healthcare Facilities*

*Presentation November 19, 2009*

**By**

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# An Update

- The original 10-Step Blueprint was published in 2006
- Primary authors were Charlotte Smith of PharmEcology Associates and Eydie Pines of H2E
- Published by Hospitals for a Healthy Environment
- The Bay Area Pollution Prevention Group funded development of a California version
- In 2008, updates to the federal version were funded by EPA and incorporated into the Cal version

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# California is often a Leader in Environmental Laws

- California led the way for hazardous waste laws
- Federal government followed with RCRA law
- California and federal definitions differed
  - Result: *“California Only” hazardous wastes*
- During 1996 California Only hazardous pharmaceuticals removed from DTSC and placed under Medical Waste Management Act

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# Why We Need a California Version

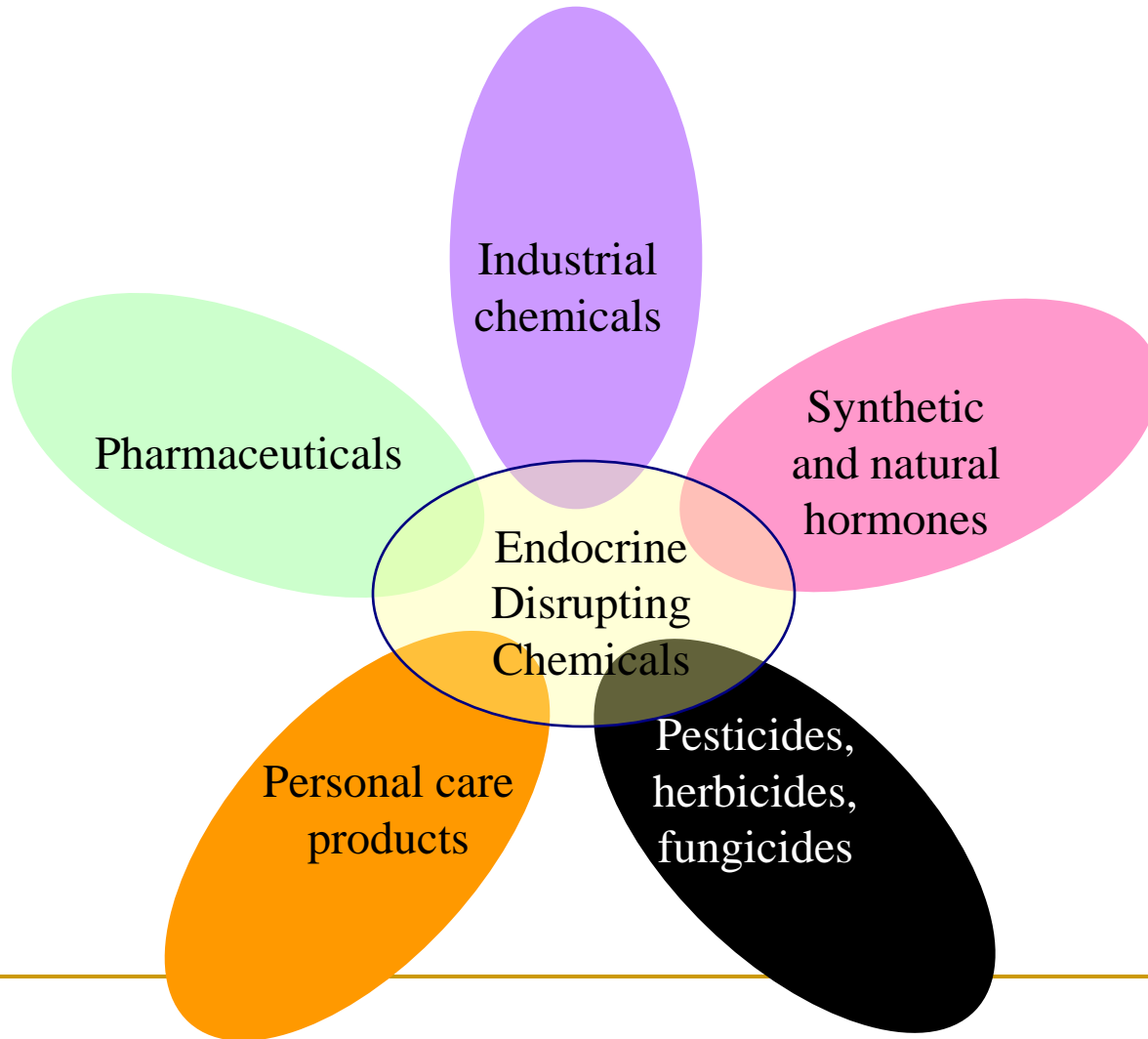
- Proper pharmaceutical waste management is a highly complex new frontier in environmental management in healthcare
  - Hospital pharmacies typically stock between 2,000 and 4,000 different items
    - Pharmaceuticals handled as RCRA hazardous wastes – P and U listed wastes and characteristic waste (D-codes)
    - California Only pharmaceuticals handled under MWMA
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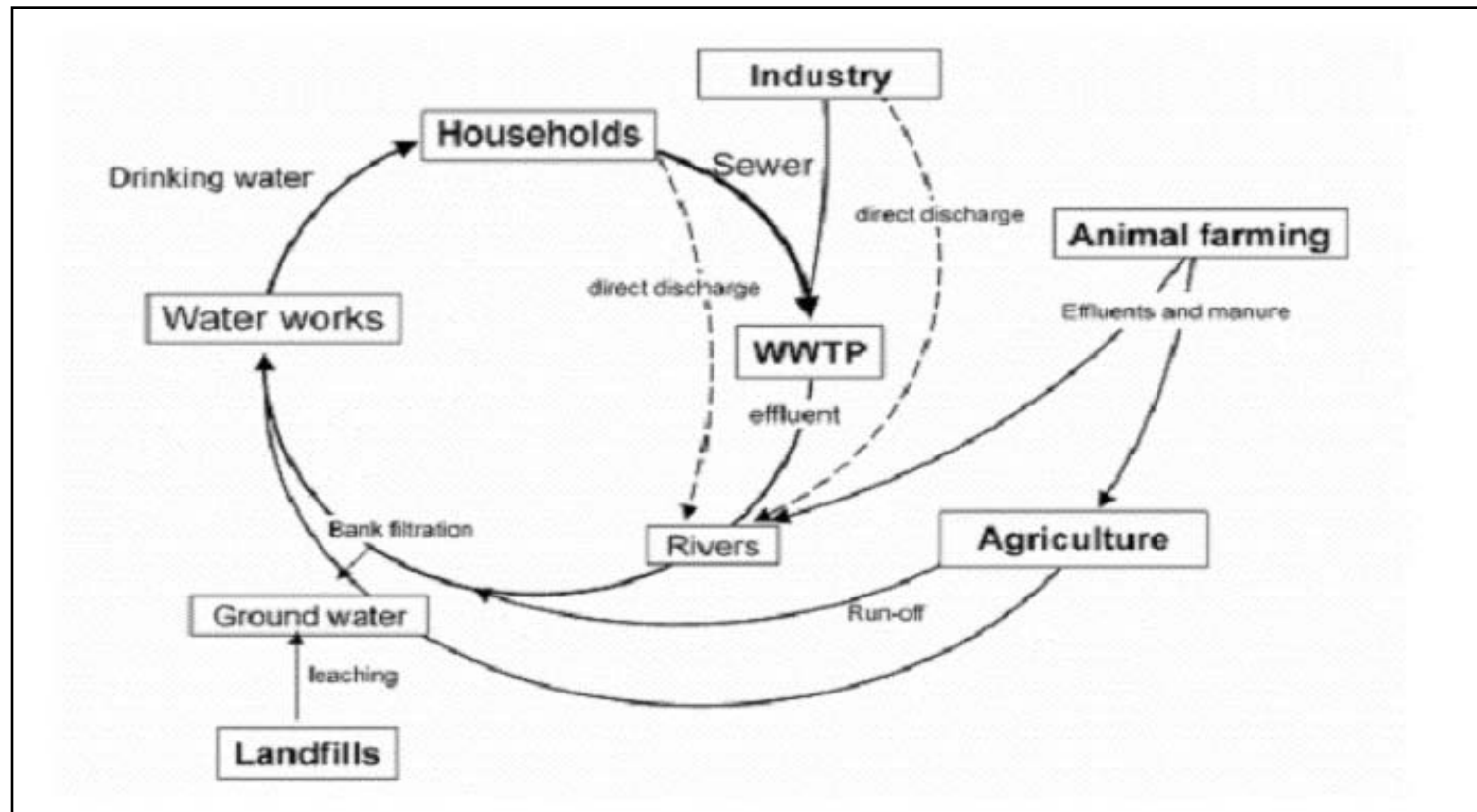
# Concerns About Pharmaceutical Disposal

- Pharmaceuticals have been found in surface and ground sources of drinking water
- Minute concentrations of endocrine disruptors have been found in waste water treatment plant receiving waters
  - Having detrimental effects on aquatic species
  - May have an impact on human health

# Endocrine Disrupting Chemicals (EDCs)



# Sources of Pharmaceuticals in Waterways



# Pharmaceuticals in the News



## Medical facilities making uncontrolled releases of controlled drugs into water

By JEFF DONN | AP National Writer 12:36 PM EDT, September 14, 2008

MINNEAPOLIS (AP) \_ In a frustrating quirk in government policy, the most tightly controlled drugs — like painkilling narcotics prone to abuse — are the ones that most often elude environmental regulation when they become waste.

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# The 10-Step Blueprint for California

- Pharmaceutical waste is not a single waste stream
- California Blueprint focus:
  - Management of RCRA & California Only hazardous pharmaceutical wastes
  - Management of non-regulated hazardous pharmaceuticals
  - Minimization of pharmaceutical waste

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# California Pharmaceutical Waste

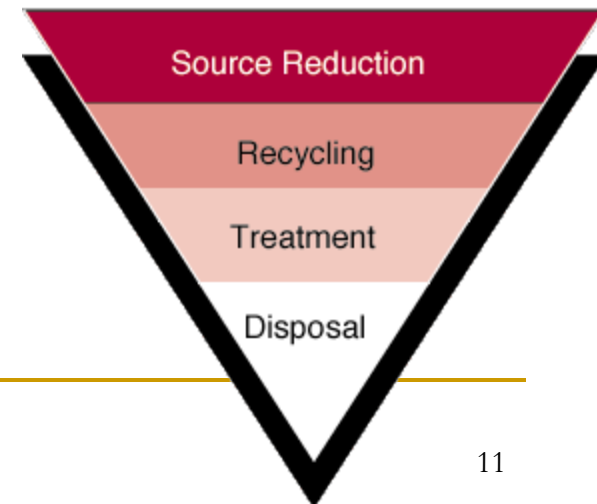
- Pharmaceutical waste is generated through a wide variety of activities
- Hospital pharmaceutical waste has been generally discarded into the sewer or landfill
- The different classification schemes for pharmaceutical wastes generated in California led to the California version of the 10-Step Blueprint

# What can we do?

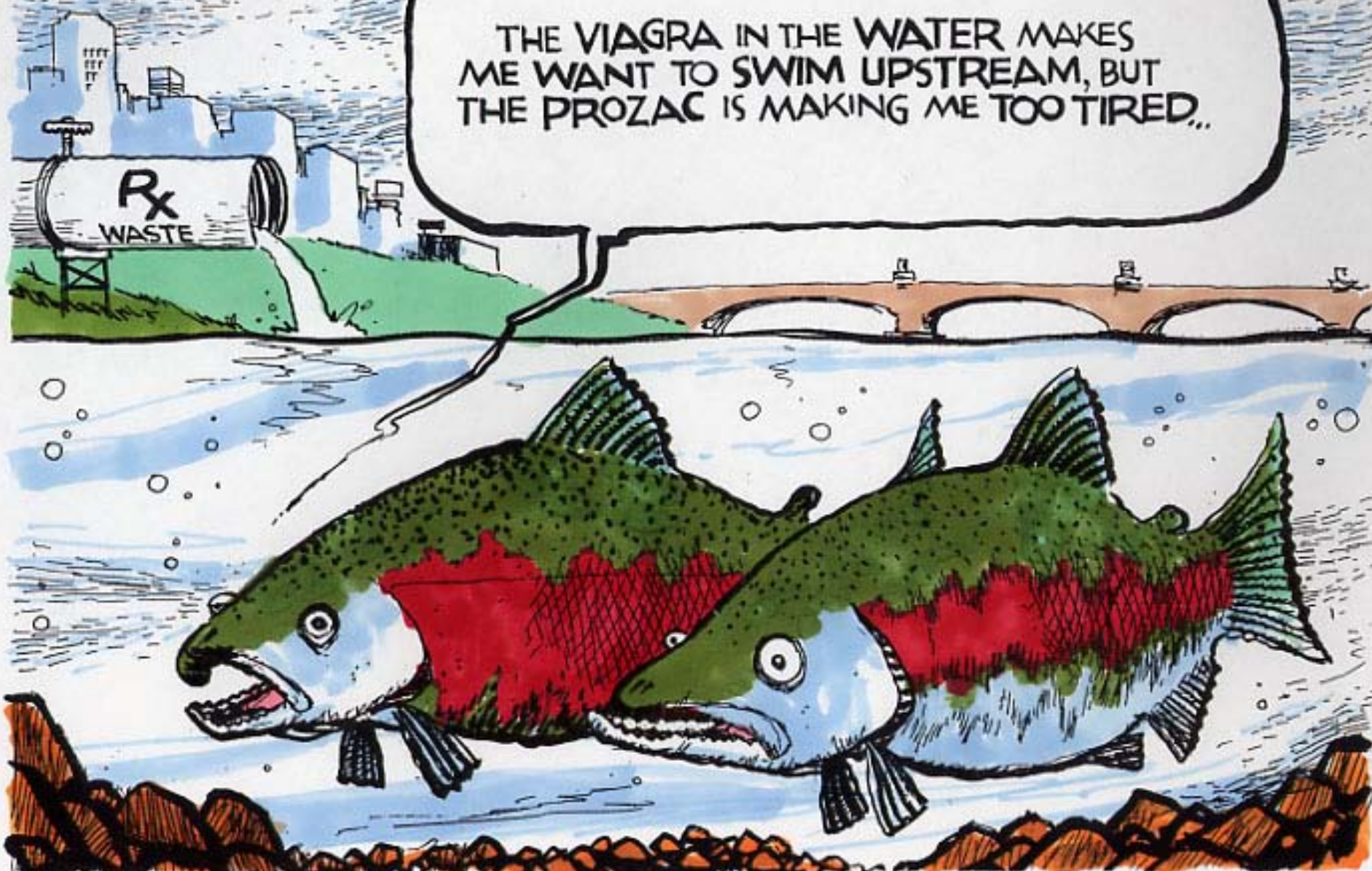
- Pollution Prevention
  - Control at source
  - Can implement & reduce loading in near term
- Product stewardship



Pollution Prevention Hierarchy



THE VIAGRA IN THE WATER MAKES ME WANT TO SWIM UPSTREAM, BUT THE PROZAC IS MAKING ME TOO TIRED..



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# The 10-Step Process

- Step 1 Take immediate actions
- Step 2 Overview of laws governing pharmaceutical wastes
- Step 3 Guidance in handling non-regulated pharmaceutical wastes
- Step 4 Perform a drug inventory
- Step 5 Pharmaceutical waste minimization
- Step 6 Generator status and department reviews

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# The 10-Step Process

- Step 7 Communication and labeling
- Step 8 Management options
- Step 9 Implementation process
- Step 10 Launching the program

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# Step #1: *Take Immediate Action/ Get Started*

- Establish a committee of stakeholders
  - Can use existing Committee (i.e.; EH&S)
  - Must include: Pharmacy, EVS, Nursing, Infection Control, Education,
  - Others to consider: Safety, Engineering, Administration, Laboratory, Purchasing/Materials Management
- Get support from Senior Management
- Keep Senior Management informed

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## Step #2: *Know the Laws Governing Pharmaceutical Waste Disposal*

- Federal RCRA Hazardous Waste
- DTSC definitions became “*California Only*” hazardous waste and pharmaceuticals under this definition must be handled as Medical Waste sent for incineration
- Non-RCRA and non-California only hazardous waste may still have sewer or landfill bans and ***best management practices: send it to medical waste incineration***

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# Key Issues

- Federal change in status of epinephrine salts being regulated as a P-listed RCRA waste (October 15, 2007)
- Expansion of the epinephrine syringe exclusion to other P and U-listed wastes (April 2008)
- EPA proposed amendment to Universal Waste Rules to include pharmaceuticals (March 4, 2009 comment period ended)

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# Epinephrine Salts Regulation Changes

- Epinephrine salts were RCRA P-listed 042 hazardous waste
- October 15, 2007 EPA memo:
  - EPA acknowledged that most if not all of the chemical used in hospitals was one of the several epinephrine salts
  - EPA determined that the scope of the P042 listing of epinephrine **does not** include epinephrine salts

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# Epinephrine Salts Regulation Changes

- Since this clarification epinephrine salts can be handled as a California Only hazardous waste eligible for treatment as medical waste in California
- ***Best Management Practice:*** Handle epinephrine salts as medical waste and send for treatment in a medical waste incinerator

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# Expansion of Epinephrine Syringe Exclusion

- December 1994 EPA Hotline interpretation:
  - Determined that excess and residue epinephrine in a syringe after the proper dose had been administered to a patient was the ***single pharmaceutical exemption*** to the phrase not used for its intended purpose
  - This allowed syringes that had contained epinephrine to be placed in a regular sharps container and **not sent as RCRA hazardous waste**

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# Expansion of Epinephrine Syringe Exclusion

- EPA published an interpretive letter on April 14, 2008:
  - Extended the exemption to other P and U-listed drugs administered by syringe
  - Did not include contents of unused syringes
  - Use did include both patient injection and transfer of product by syringe from a vial to an IV
  - Only covered syringe as a dispensing device

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# Trace Chemotherapy Waste

- Federal RCRA law does not address “*trace chemotherapy*” waste; but the California Medical Waste Act does.
- The Medical Waste Management Act requires that trace chemotherapy waste be sent for incineration at a medical waste incineration facility
- Bulk chemotherapy waste must be sent to a RCRA facility

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# Nitroglycerin Exclusion

- Nitroglycerin is listed as a RCRA waste solely based on its reactivity characteristic
- In 2001 a revision to the mixture and derived from rules excluded all P- and U-listed wastes listed solely for ignitability, reactivity, and corrosivity characteristics (including mixtures, derived-from and as generated wastes) once they no longer exhibit the characteristic
- This action removed nitroglycerin from the P-listed waste as it is weak and non-reactive

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## Step #3: *Best Management Practices for Non-Regulated Pharmaceuticals*

- Many drugs of concern to EPA & CDC are not currently regulated
  - Hormones
  - Antibiotics
  - Antidepressants
  - Antihypertensives
- Some are regulated in California under Medical Waste Management Act
- Best Management Practice: **Send to Medical Waste Incinerator**

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# Incinerate as Medical Waste

- Formulations with a listed active ingredient that is not the sole active ingredient
- Non-chemotherapy drugs that meet NIOSH Hazardous Drug Criteria
- Therapeutic drugs meeting NIOSH Criteria
- Drugs listed in Appendix VI of OSHA Technical Manual
- Drugs with LD<sub>50</sub> that are less than 50 mg/kg
- Vitamin/mineral preparations with heavy metals
- Endocrine disruptors

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# Best Management Practice

- Destruction by incineration of all discarded drugs is BMP at this time
- Eliminate drain disposal
- Eliminate landfilling

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## Step #4: *Perform a Drug Inventory*

- Most hospital pharmacies stock 2,000-4,000 drugs
  - 5% of the inventory are RCRA hazardous
  - Most chemotherapy drugs are not RCRA but should be managed as a hazardous waste as a best management practice
  - California's MWMA requires non-RCRA, "California-Only" hazardous waste to be sent to a medical waste incinerator for treatment
- RCRA places burden of hazardous waste determination on the generator

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# Drug Waste Determinations

- Gather drug specific data
  - Hospital's formulary
  - Drug purchasing for non-formulary drugs
    - Check the past 12 months purchasing records
  - National Drug Code
  - Brand name
  - Generic name
  - Manufacturer
  - Strength
  - Dosage form
  - Package size

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# Identify Ingredients and Waste Determination

- Determine all ingredients found in each drug
  - Include: preservatives, heavy metals and alcohol
- Consider all compounded items, reformulations and IV admixtures
  - May change the hazardous waste characteristic and must be considered in your determination
- Make the waste determination
  - RCRA
  - Hazardous by BMP
  - California-Only medical waste

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# Other Points to Remember

- Document all your decisions to support you in an audit
- Keep the review current
- Services of other companies to do this work
- Subscription on-line web search engines can assist in the determination process

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## Step #5: *Minimizing Pharmaceutical Waste*

- Determine what pharmaceuticals are being wasted
- Determine why they are being wasted
- Explore strategies to reduce their wasting
- Source reduction can:
  - Minimize compliance issues
  - Lower costs
  - Reduce liability

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# Pharmaceutical Waste Minimization

- Consider lifecycle impacts in purchasing process
  - ❑ Don't accept drugs with less than one year dating if you can
  - ❑ Select products with less packaging
  - ❑ Select drugs without mercury or m-cresol preservatives – use single dose if necessary
  - ❑ Work with your GPO to influence manufacturers

# Pharmaceutical Waste Minimization

- Maximize the use of opened chemotherapy vials – look for ways to maximize usage of partial vials to minimize waste
- Implement a physician samples policy
  - Document the amount and cost of disposal of samples
  - Include staff time to review sample dating and waste characterization
  - Move to a tighter (or NO samples) policy; move to drug vouchers

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# Pharmaceutical Waste Minimization

- Labeling drugs for home use can reduce wastage of ointments/inhalers
  - Must have a discharge Rx
  - Must label for home use
  - Consider using pre-authorized discharge orders
  - Consider relabeling for home use
- Priming and flushing IV lines with saline
  - Flushing chemotherapy IV lines with saline allows bag and lines to go as trace chemotherapy waste

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# Pharmaceutical Waste Minimization

- Examine the size of the container relative to use
  - Survey of all drugs routinely wasted due to the prepared product being too large for complete administration
  - Changes to smaller doses can save money and reduce waste
  - If the product size you need isn't available, work with your GPO

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# Pharmaceutical Waste Minimization

- Replace prepackaged unit dose liquids with patient-specific oral syringes
  - Especially try this in the neonatal and pediatrics units
  - Review all Emergency Department multi-dose vials to determine the optimum dosage unit to stock based on usage and consider moving to single dose syringes to avoid possible mercury preservatives and partial use

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# Pharmaceutical Waste Minimization

- Monitor dating on emergency syringes
  - Move epinephrine and nitroglycerin syringes on crash carts by moving to emergency rooms for use prior to expiration on crash carts
- Create tight inventory controls to limit the amount of original manufacturers' containers and repacks that expire before use
- Staff time spent managing expired products is a cost that should be avoided

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# Step #6: Generator Status and Departmental Reviews

- Perform department reviews to gain information on waste generation and disposal practices for pharmaceuticals
  - Establishes a baseline to measure progress
  - Can use an informal interview process
    - Helps determine uniformity in handling pharmaceutical wastes
    - Identifies where policies and procedures have been established
    - Opportunity to obtain ideas from staff on waste minimization
  - Data can be gathered from dispensing cabinets

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# Generator Status and Departmental Reviews

- Conduct a frequency analysis
  - Which drugs are dispensed to each unit
  - Use dispensing software if available
  - Review with pharmacy staff if dispensing software not available to determine where 5% of RCRA drugs go
    - Provides information on which units have potential to generate hazardous waste
    - Targets where to start roll-out of improved handling practices to minimize wastes produced

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## Step #7: Communication and Labeling Challenge

- Must communicate the waste status of the pharmaceuticals handled at your facility
  - Segregate RCRA hazardous waste and bulk chemotherapy waste into hazardous waste containers and ship off as hazardous waste
  - Segregate the rest as California-Only pharmaceutical waste and ship off as medical waste
    - Label “INCINERATE ONLY”

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# Communication and Labeling Techniques

- Automating Disposition Data in the Labeling Process
  - Incorporating into dispensing hardware
    - Waste segregation data incorporated into patient label
    - Incorporate disposition practices into automated dispensing cabinet systems
  - Incorporate into bedside barcode system to notify nurses of disposition requirements
- Manually labeling disposition information in the pharmacy

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# Communication and Labeling Techniques

- Provide guidance on the Nursing Units
  - Clearly label hazardous pharmaceutical waste containers
  - Display guidance on posters near the containers
- Use a code name on the label
  - Should be easy for staff to remember, but doesn't alarm patients
  - Include discard location
  - Train on how the container is to be managed

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## Step #8: *Consider Management Options*

- Four models for managing pharmaceutical wastes
  - Automated bar-code driven sorting
  - Electronic labeling in nursing units
  - Manual labeling in nursing units
  - Managing all pharmaceutical wastes as RCRA hazardous wastes
- A fifth model included in the original Blueprint segregates at a central storage accumulation area. CDPH does NOT approve this method due to MWMA requirements that medical waste be contained separate from other wastes

# *Consider Management Options*

- First three models segregate at the point of generation
  - Segregate RCRA as hazardous waste and label: “Hazardous Waste”
  - Segregate California-Only hazardous waste as medical waste labeled: “INCINERATE ONLY”
- Fourth model segregates all pharmaceutical wastes as RCRA hazardous waste
  - This is a costly approach to take

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## Step #9: *Getting Ready for Implementation*

- To maximize compliance, establish satellite accumulation sites as close as possible to where pharmaceutical wastes are generated
  - Pharmacies – locate hazardous and California Only hazardous pharmaceutical containers in clean room and main pharmacy
  - Nursing units – locate in soiled utility rooms, medication rooms, medication carts
  - Patient rooms – locked wall units if needed

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# *Getting Ready for Implementation*

- Containers must be spill-proof, leak-proof, properly labeled for the waste stream
  - Hazardous waste
  - INCINERATE ONLY for medical waste pharmaceuticals
- Keep containers closed when not in use
  - Consider using wire frames with foot pedals to open/shut the container

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# *Getting Ready for Implementation*

- Evaluate the hazardous waste storage area
  - The place where satellite hazardous wastes are moved for storage before transport offsite
  - Specific requirements for these areas
  - Your facility may already have a central storage area
    - Make sure there is room for pharmaceutical wastes
    - May need a second area or enlarge the first one
- California Only hazardous pharmaceutical wastes can be stored with regulated medical waste

# *Getting Ready for Implementation*

- Select the right vendor
  - ❑ Permitted hazardous waste vendor for RCRA and bulk chemotherapy wastes
  - ❑ Permitted medical waste hauler for California Only hazardous waste pharmaceuticals and all other pharmaceuticals being handled in this manner as a Best Management Practice
  - ❑ Reverse distributors are NOT waste management services
  - ❑ They can take products in original manufacturer's packaging that are eligible for credit

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# *Getting Ready for Implementation*

- Conduct a pilot program to find bugs and refine program
  - Suggest pilot program be carried out in:
    - Pharmacy
    - In-patient oncology units
    - Outpatient oncology units
  - Develop new policies and procedures
  - Be prepared for spills
    - First Responder Awareness (FRA) and First Responder Operational (FRO) training
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## Step #10: *Launching the Program*

- A successful pharmaceutical waste management program depends on the participation of all employees
- Conduct just-in-time training to roll out the program
- Also use Safety Fairs, Nursing Education Expos and other hospital-wide events to train
- Must train all three shifts and have every thing in place for the roll out

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# *Launching the Program*

- Complete hazardous waste manifests – two approaches
  - Hospitals can provide their vendors with all P, U, and D waste codes being used and the vendor pre-certifies the list and creates a waste profile and certified waste stream
  - Nursing and pharmacy staff need to document what is discarded in each container
- Use the assistance of your vendor but the generator is ultimately responsible

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# *Launching the Program*

- Complete a medical waste tracking document for all non-RCRA, California Only pharmaceutical wastes being sent to a medical waste incinerator
- Track and measure progress

QUESTIONS??