

MANAGING PHARMACEUTICAL WASTE

TO ENSURE
REGULATORY COMPLIANCE AND ENVIRONMENTAL RESPONSIBILITY



PRESENTED BY:

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FOREWORD

The following information is provided to increase awareness of the Environmental and Regulatory issues involved with the Generation and Disposal of Pharmaceutical Waste.

The information is useful for review and for modification of current policies and procedures to ensure compliance with State and Federal Environmental Regulations.

INTRODUCTION:

- The proper identification, segregation and disposal of hazardous chemical waste, including waste pharmaceuticals, carries heavy corporate and personal liability, along with a civic responsibility to protect the environment.
- Corporate fines of up to \$32,500 per violation per day can be levied.
- As the U.S. Environmental Protection Agency and the CT. Department of Environmental Protection begin to scrutinize hospital waste streams more closely, it is critical that health care professionals ensure that best management practices are reviewed and updated in this important area.
- While the Pharmacy Department is central to managing Pharmaceutical Waste, multiple departments, including Safety and Risk Management, Infection Control, Nursing, Operating Room, Emergency Department, Engineering, Environmental Services, and Administration, must understand the appropriate processes.

OVERVIEW OF THE PROBLEM

- In the past, the primary goals regarding Pharmaceutical Waste were to ensure that residual drugs were rendered unrecognizable and unrecoverable, to prevent accidental poisoning and to deter illegal diversion.
- Common disposal practices included disposal through sinks and drains to municipal sewers and water treatment facilities and disposal in hospital or municipal incinerators.

OVERVIEW OF THE PROBLEM

- Pharmaceutical Waste is commonly discarded as infectious or Biomedical Waste, collected in red sharps containers or red bags. **This is an inappropriate and potentially illegal practice.**
- Pharmaceuticals are chemicals and many of them are regulated under the 1976 Resource Conservation and Recovery Act (**RCRA**). Most others are prohibited from disposal in the trash or down the drain by Connecticut Statute.

INAPPROPRIATE DISPOSAL OF PHARMACEUTICAL WASTE

CAUSES CONTAMINATION OF SURFACE AND GROUND WATERS:

- AFFECTS MUNICIPAL SEWER AND WATER TREATMENT FACILITIES AS CONTAMINANTS ADVERSELY AFFECT THE “GOOD BACTERIA” REQUIRED TO TREAT AND PURIFY WASTE WATER.
- A U.S. GEOLOGICAL SURVEY REPORT NOTED THAT OF 139 WATER STREAMS SAMPLED IN THE U.S., 80% CONTAINED ORGANIC CONTAMINANTS, MANY OF WHICH WERE PHARMACEUTICALS FROM COMMON PRESCRIPTION AND OVER-THE-COUNTER PRODUCTS.
- Copy available at: <http://toxics.usgs.gov/regional/emc>

EFFECTS OF INAPPROPRIATE DISPOSAL

RECENT WORK ON ENDOCRINE DISRUPTORS PRESENTED IN THE BOOKS “**OUR STOLEN FUTURE**” AND “**GENERATIONS AT RISK**” RAISE AN EVEN GRAVER THREAT.

MINISCULE LEVELS OF CHEMICALS THAT MIMIC DEVELOPMENTAL HORMONES SUCH AS ESTROGEN, TESTOSTERONE, AND THYROID CAN **CAUSE DEVASTATING RESULTS IN THE FETUS AND NEWBORN.**

OTHER EFFECTS OF INAPPROPRIATE DISPOSAL

- **OTHER EFFECTS INCLUDE:**

- ✓ INFERTILITY-LOW SPERM COUNTS (50% REDUCTION SINCE 1939).
- ✓ HORMONALLY TRIGGERED HUMAN CANCERS.
- ✓ NEUROLOGICAL DISORDERS IN CHILDREN.
- ✓ HYPERACTIVITY, ATTENTION DEFICIT DISORDER.
- ✓ GENITAL DEFORMITIES.
- ✓ LOWERED IQ, RAGE REACTION.
- ✓ DEVELOPMENTAL & REPRODUCTIVE PROBLEMS IN WILDLIFE.

CATEGORIES OF PHARMACEUTICAL WASTE

- **RCRA WASTE PHARMACEUTICALS –**
THESE ARE MEDICATIONS WHICH INCLUDE:
HAZARDOUS P-LISTED, U-LISTED, & D-LISTED OR
CHARACTERISTIC WASTE.
ALSO INCLUDES CERTAIN MATERIALS THAT HAVE BEEN IN
CONTACT WITH THE ABOVE MEDS.
- **ALL WASTE ANTIBIOTICS -**
INCLUDES ALL RESIDUAL OR BULK AMOUNTS OF
ANTIBIOTICS AND SHARPS, BOTTLES, IV BAGS & TUBING
THAT HAVE BEEN IN CONTACT WITH THE ABOVE MEDS.
- **CONTROLLED SUBSTANCES WASTE –**
MUST BE RENDERED NON-RECOVERABLE.

RCRA WASTE PHARMACEUTICALS*

➤ **P-LISTED WASTES -**

EXAMPLES: EPINEPHRINE, NITROGLYCERIN, NICOTINE, COUMADIN / WARFARIN (>0.3%), ARSENIC TRIOXIDE, PHYSOSTIGMINE, PHYSOSTIGMINE SALYCLATE, AND PHENTERMINE.

➤ **U-LISTED WASTES -**

EXAMPLES: CYCLOPHOSPHAMIDE, MELPHELAN, LINDANE, SACCHARIN, URACIL MUSTARD, COUMADIN / WARFARIN (<0.3%).
BMP: ALL CHEMO. AGENTS ARE TREATED AS RCRA HAZ. WASTE.

➤ **D-LISTED WASTES -**

WASTES THAT EXHIBIT THE CHARACTERISTICS OF IGNITABILITY, TOXICITY, CORROSIVITY, & REACTIVITY.

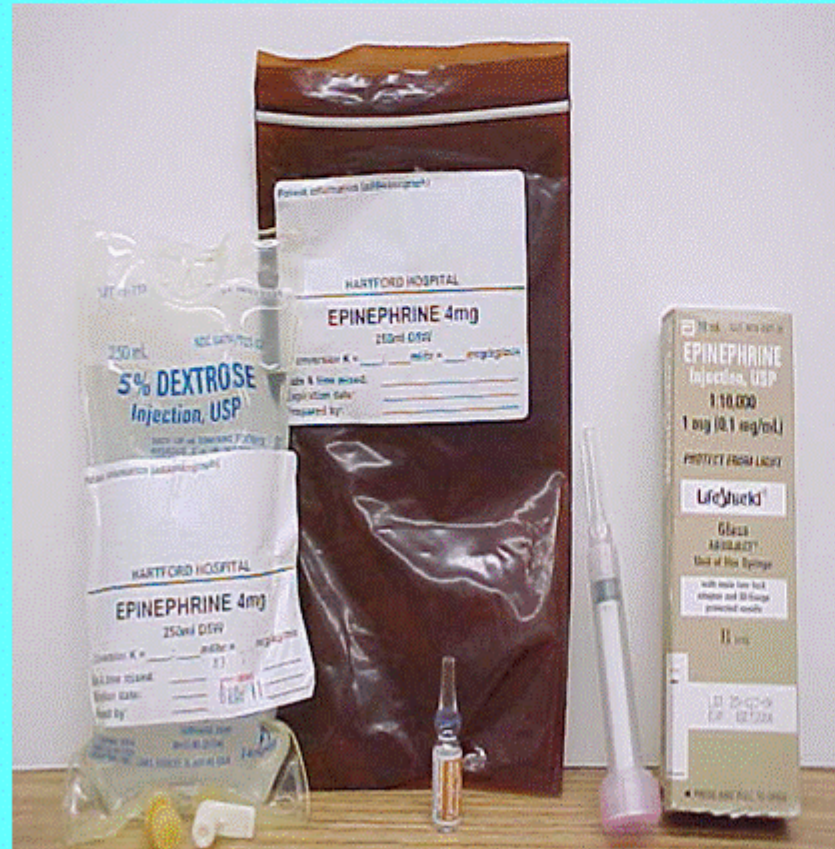
EXAMPLES: INSULIN, SILVER NITRATE, BARIUM, MERCURY, STRONG ACIDS AND BASES, NITROGLYCERIN.

➤ *EXAMPLES ONLY: CHECK YOUR CHEMICAL FORMULARY!

INSULIN & CHEMOTHERAPEUTIC AGENTS

- **Must not** be disposed of via sinks and/or drains and ultimately to Sewers and Water Treatment Facilities.
- Waste Insulin and Chemotherapeutic Agents, residual or bulk amounts, and associated sharps, bottles, vials, IV bags and tubing **should** be disposed of in **RCRA Hazardous Waste Containers**.

RCRA WASTE PHARMACEUTICALS



WASTE ANTIBIOTICS

- **Must not** be disposed of via sinks and/or drains and ultimately to Sewers and Water Treatment Facilities.
- Antibiotics associated with sharps, bottles, vials, IV Bags & Tubing used in the administration of these medications **should** be disposed of in **Pharmaceutical Biomedical Waste Containers.**
- Bulk unused pharmaceuticals are CT Regulated Waste managed by pharmacy.

CONTROLLED SUBSTANCES & DEA WASTE

- **Must not** be disposed of via sinks and / or drains.
- **Should** be returned to the Central Pharmacy for disposal.
- Bulk Waste will be deposited in Controlled Substances Waste Containers, which contain an approved chemical compound that renders the Controlled Substances Waste **Non-Recoverable**.
- The Controlled Substances Containers are located in the Pharmacy's Controlled Substances Vault.
- Residual Waste Amounts can be deposited in **Pharmaceutical Waste Sharps Containers**.



Non-Biomedical, Non-RCRA Hazardous Pharmaceutical Waste

- **Includes:**
 - Bulk Waste Antibiotics.
 - Bulk DEA Controlled Substances.
 - Other bulk Pharmaceuticals.
- **Are Connecticut Regulated Wastes/Special Wastes.**
- **Returned to Pharmacy – for collection / treatment.**
- **Must be sent to an approved disposal facility:**
 - Hazardous Waste Disposal facility.
 - Connecticut Regulated Waste facility.
 - Authorized MSW Incinerator.
 - Out-of-state facility complying with its state's requirements.

WHERE IS PHARMACEUTICAL WASTE GENERATED?

- PHARMACY / SATELLITES
- PATIENT CARE UNITS
- INTENSIVE CARE UNITS
- OPERATING ROOM
- EMERGENCY DEPARTMENT
- ONCOLOGY / HEMATOLOGY
- OTHER OUTPATIENT CLINICS



HOW IS PHARMACEUTICAL WASTE GENERATED?

- IV PREPARATION
- GENERAL COMPOUNDING
- SPILLS / BREAKAGE
- PARTIALLY USED VIALS, SYRINGES, IV'S
- CONTAMINATED BIOMEDICAL WASTE
- DISCONTINUED, UNUSED PREPARATIONS
- UNUSED REPACKS (UNIT DOSE)
- PATIENTS' PERSONAL MEDICATIONS
- OUTDATED PHARMACEUTICALS



PHARMACEUTICAL BIOMEDICAL WASTE DISPOSAL CONTAINERS

- **SMALL VOLUME CONTAINERS:**
White Lockable Cabinets
with Blue “mail slot” top openings.



PHARMACEUTICAL BIOMEDICAL WASTE DISPOSAL CONTAINERS

- **MEDIUM VOLUME CONTAINERS:**
Purple tops, gasket
with / without large gray drop tray.



RCRA HAZARDOUS WASTE DISPOSAL CONTAINERS

- **SMALL VOLUME CONTAINERS:**
Black Containers with White lids.
2 gallon
Labeled - “RCRA HAZARDOUS WASTE”



RCRA HAZARDOUS WASTE DISPOSAL CONTAINERS

- **LARGE VOLUME CONTAINERS:**
Black containers with White Lids.
17 gallon / 8 gallon
Labeled - “RCRA HAZARDOUS WASTE”



LOCATIONS OF DISPOSAL CONTAINERS

- Patient Rooms
- Intensive Care Rooms
- Medication Rooms
- Medication Carts
- Crash Carts
- Operating Suites
- Pharmacy/Satellites



WASTE STREAM DISPOSAL POSTERS

- **Black Bordered -**
“RCRA HAZARDOUS WASTE CONTAINERS”
- **Purple Bordered -**
“DANIELS SHARPSMART - FOR INCINERATION”
- **Red Bordered -**
“BIOMEDICAL WASTE CONTAINERS”
- **Green Bordered -**
“SOLID WASTE CONTAINERS”

RCRA HAZARDOUS WASTE CONTAINERS

HAZARDOUS P - LISTED MEDS

EPINEPHRINE NITROGLYCERIN ARSENIC TRIOXIDE

NICOTINE PHYSOSTIGMINE WARFARIN (COUMADIN)

HAZARDOUS U - LISTED MEDS

ALL RESIDUAL OR BULK CHEMO

HAZARDOUS D - LISTED MEDS

ALL RESIDUAL OR BULK INSULIN

ALL

SHARPS, BOTTLES, IV BAGS & TUBING, TABLETS / PILLS
THAT HAVE CONTAINED OR BEEN IN CONTACT WITH THE ABOVE MEDS
MUST BE DISCARDED IN THIS SHARPS CONTAINER.
DO NOT DRAIN OR EMPTY ANY RESIDUAL CONTENTS ANYWHERE
INCLUDING THE SINK OR DRAINS.

These containers are checked every 24 hours and must be removed by
authorized personnel only.

If you need a change-out immediately, please call: EXT. 2855

RCRA Waste Containers

Black Containers, white lids labeled - "RCRA HAZARDOUS WASTE"



All Hazardous Waste as listed below:

- Insulin
- Epinephrine
- Nitroglycerin
- Nicotine
- Physostigmine
- Warfarin (Coumadin)
- Chemotherapy agents

All sharps, bottles, IV bags & tubing, tablets/pills that have contained or been in contact with the above meds must be discarded in this sharps container

Do NOT drain or empty any residual contents anywhere including the sink or drains

These containers are checked every 24 hours and must be removed by authorized personnel only.

If you need a change out immediately call 5-2855

DANIELS SHARPSMART - FOR INCINERATION

BIOMEDICAL WASTE

USED / UNUSED SHARPS

BIOMEDICAL PHARMACEUTICALS / MEDS

ALL WASTE MEDICATIONS / ANTIBIOTICS

AND

ASSOCIATED SHARPS

ALL

SHARPS, BOTTLES, IV BAGS & TUBING, TABLETS / PILLS
THAT HAVE CONTAINED OR BEEN IN CONTACT WITH THE ABOVE MEDS
MUST BE DISCARDED IN THIS SHARPS CONTAINER.

DO NOT DRAIN OR EMPTY ANY RESIDUAL CONTENTS ANYWHERE
INCLUDING THE SINK OR DRAINS.

These containers are checked daily and can be removed and replaced as needed.

If you need a change-out immediately, please call: EXT. 2855

Daniels Sharpsmart

Purple top container, gasket, with/without large gray drop tray



All waste as listed below belong in these containers:

- Biomedical Waste sharps
- Used / Unused sharps
- All Pharmaceuticals:
Medications / Antibiotic Waste

All sharps, bottles, IV bags & tubing, tablets/pills that have contained or been in contact with the above meds must be discarded in this sharps container.

Do NOT drain or empty any residual contents anywhere including the sink or drains.

These containers are checked daily and can be removed and replaced as needed.

If you need a change out immediately call 5-2855

BIOMEDICAL WASTE CONTAINERS

BIOMEDICAL WASTE

BLOOD / BODY FLUID SATURATED PRODUCTS ISOLATION WASTES

ANATOMICAL / PATHOLOGICAL WASTE CULTURES AND STOCKS

ANIMAL CARCASS / BEDDING

ALL

**IV BAGS & TUBING WITH VISIBLE BLOOD / BLOOD PRODUCTS AND
OTHER ITEMS SATURATED OR CAKED WITH BLOOD / BODY FLUIDS
CAN BE DISCARDED IN THIS BIOMEDICAL WASTE CONTAINER.**

PLEASE NOTE THAT BULK BLOOD CAN BE DISCARDED VIA THE SINK DRAIN.

These containers are checked frequently and can be removed and replaced as needed.

If you need a change-out immediately, please call: EXT. 2855

SOLID WASTE CONTAINERS

SOLID WASTE

Paper Towels.

Wrapping and Packaging materials.

ExamGloves, Masks, Disposable Gowns, Gauze, Bandages, Dressings, etc.

not grossly soiled with **Biomedical** material.

I.V. Tubing only - minus spike
from I.V. Bags
(**Not RCRA, INSULIN, ANTIBIOTICS, or BLOOD**)

Food and food container items.

EXCLUDES ALL WASTE DESIGNATED AS OR CONTAMINATED WITH:

RCRA HAZARDOUS WASTE

PHARMACEUTICAL BIOMEDICAL WASTE

BIOMEDICAL WASTE

CONFIDENTIAL WASTE

These containers are checked frequently and can be serviced as needed.

If you need service immediately, please call: EXT. 2855

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EXCLUDES ALL WASTE DESIGNATED AS OR CONTAMINATED WITH:

RCRA HAZARDOUS WASTE

PHARMACEUTICAL BIOMEDICAL WASTE

BIOMEDICAL WASTE

CONFIDENTIAL WASTE

These containers are checked frequently and can be serviced as needed.

If you need service immediately, please call: EXT. 2855

SUMMARY:

Important Things to Remember When Managing Pharmaceutical Waste

- **Any organization, other than households, must identify, segregate, document, properly store, manifest, transport, and dispose of RCRA Hazardous Waste properly.**
- **Hazardous Pharmaceutical Waste cannot be disposed of through sewerage, landfilling, or municipal incineration by a medical waste treatment plant (incineration or sterilization).**
- **It must be transported in Department of Transportation approved containers to a Federally permitted RCRA incinerator.**
- **Quantities generated per month by an organization must be documented.**
- **Considering both the serious corporate and personal liability associated with violating RCRA and the societal threat posed by inappropriate disposal, it is time for health care facilities to bring their current Pharmaceutical Waste disposal practices into line with evolving best management practices.**
- **The key to successful management is the development and implementation of consistent practices that promote the identification and appropriate disposal of Hazardous Pharmaceutical Waste.**

SUMMARY:

Additional Things to Remember

- **Non-RCRA Hazardous Pharmaceuticals must not be placed in regular trash or put down the drain.**
- **Ensure that your Biomedical Waste Management Plan is revised to address the segregation of the different wastes you generate, including specific procedures for handling such waste, employee training, treatment and disposal as applicable.**
- **Be careful to segregate Biomedical Waste from RCRA Hazardous Waste, Radiological Waste, and other Solid Wastes (including CT-Regulated Wastes).**
- **You may implement an Integrated Infectious Waste Management Plan that includes OSHA's Exposure Control Plan requirements and DEP's Biomedical Waste Management Plan requirements.**

ADDITIONAL BENEFITS

- JCAHO Performance Improvement Initiative for Environmental of Care and Medication Management.
- Establishes organizational compliance with **RCRA**.
- Establishes organizational compliance with the **Clean Air and Clean Water Act**.
- Reduces **CT. DEP** and **EPA** liability and risk exposure to a minimum.
- Protects employees and patients.
- Demonstrates responsible care in dealing with **Hazardous Substances and Hazardous Wastes**.
- Knowledge gained can be applied to Hospital Disaster Planning and Chemical Spill Response Protocol.
- Employing Best Management Practices such as better inventory control and automated dispensing reduces product acquisition and waste disposal costs.

CONTACTS / REFERENCE INFORMATION

- State of Connecticut
Department of Environmental Protection
Bureau of Materials Management and Compliance Assurance
Waste Engineering and Enforcement Division
79 Elm Street, Hartford, CT. 06106-5127
<http://www.ct.gov/dep>, COMPASS Program (888) 424 - 4193
- Pharmaceutical Waste -
Ross Bunnell, ross.bunnell@po.state.ct.us, (860) 424 - 3274
- Biomedical Waste -
Mark Latham, mark.latham@po.state.ct.us, (860) 418 - 5930
- Wastewater Management -
Chris Malik, christopher.malik@po.state.ct.us, (860) 424-3959