MARTIN LUTHER KING, JR. OUTPATIENT CENTER (MLK-OPC)
POLICY AND PROCEDURE

DIVISION: ENVIRONMENT OF CARE	**NUMBER: 5.601**
SUBJECT: PHARMACEUTICAL WASTE MANAGEMENT	
SECTION: PHYSICAL PLANT	**Page 1 of 12**
REVISED BY: SAFETY OFFICER & POLICY AND PROCEDURES COMMITTEE	**EFFECTVE DATE:** 04/1996
TO BE PERFORMED BY: ALL APPLICABLE STAFF	**REVISED DATE:** 12/2015, 2/24/16

I. PURPOSE

To control and manage pharmaceutical wastes in accordance with the state and federal laws and regulations

II. POLICY

Workforce must properly identify, manage, and dispose of all RCRA (Resource Conservation Recovery Act) and Non-RCRA Hazardous Pharmaceutical waste in conformance with local, State and federal laws and regulations. This policy does not apply to disposal of controlled substances. Workforce will handle pharmaceutical waste through identification, segregation, collection, and waste disposal. All appropriate interventions to minimize the quantity of pharmaceutical waste generated should be taken.

III. DEFINITIONS

Resource Conservation and Recovery Act (RCRA): The principle federal law governing the disposal of solid waste and hazardous waste. RCRA pharmaceutical waste is specifically Listed (P or U-list) or exhibits a hazardous waste characteristic (ignitable, corrosive, reactive or toxic).

Non-RCRA Hazardous Pharmaceutical Waste (California only): A pharmaceutical waste that is not “P” or “U” listed waste and does not exhibit any characteristics of hazardous waste (i.e., ignitable, corrosive, reactive, toxic).

Pharmaceutical Waste: Expired, unused, spilled, and contaminated prescription or over-the-counter human or veterinary drugs, and vaccines. The category also includes discarded items used in the handling of pharmaceuticals, such as bottles or boxes with residues, gloves, masks, connecting tubing, and drug vials.

Satellite Accumulation Area: The location where pharmaceutical wastes are initially generated.

Pharmaceutical Waste Containers: Receptacles designated specifically to receive pharmaceutical hazardous wastes.

- Black container with white lid – for RCRA hazardous pharmaceutical waste

collection and disposal.

- White container with blue lid – for Non-RCRA hazardous pharmaceutical waste collection and disposal.

- Yellow container with white lid – for chemotherapeutic waste collection and disposal.

IV. RESPONSIBILITIES

1. Pharmacy

- Develop and maintain a method (including relevant training) for identifying and managing all RCRA and non-RCRA hazardous pharmaceuticals dispensed to patient care units.

- Obtain Safety Data Sheet (SDS) from manufacturers or suppliers for each hazardous drugs it distributes.

- Assign staff to establish, manage and monitor the RCRA pharmaceutical program and to continuously update the inventory of all RCRA pharmaceuticals.

- Review RCRA pharmaceutical list regularly.

- Train all personnel who handle RCRA and Non-RCRA pharmaceutical wastes how to distinguish, segregate and dispose of these items.

- Report any hazardous pharmaceutical spills or exposures (skin or eye contact or inhalation) to their supervisors and the Safety Office or AOD after hours.

2. Satellite Areas that Generate Pharmaceutical Waste

Satellite area supervisor, area supervisor, or designee:

- Ensures that appropriate containers are available to dispose of pharmaceutical wastes generated in the unit. If the container is not available, the supervisor will contact Environmental Services for a replacement.

- Coordinates the collection, storage and removal of all pharmaceutical wastes.

- Ensures that all pharmaceutical waste containers are securely closed, are in good condition, and are properly labeled. The initial date that hazardous pharmaceutical waste is placed in the container must be clearly marked and visible on all containers used for "satellite" accumulation.

- Notifies EVS when pharmaceutical waste containers are ¾ full or reach one year (1 quart or 2 pounds for P-listed waste).

- Ensures that employees are aware of the procedures outlined in this policy.

- Ensures that appropriate personal protective equipment is available to and worn by employees.

- Ensures that all unit staff who handle pharmaceutical waste are properly trained.

- Reports any hazardous pharmaceutical spills or exposures (skin or eye contact or inhalation) to their supervisors and the Safety Office.

3. Environmental Services (EVS)

- Purchase pharmaceutical waste containers and delivers them to the satellite areas where pharmaceutical wastes are generated.

- Remove pharmaceutical waste containers promptly when ¾ full

(Maximum one year at satellite accumulation or one quart for P-listed). Replace with empty containers.

- Transport RCRA pharmaceutical waste to hazardous waste storage facility and non-RCRA hazardous pharmaceutical waste to the medical waste storage area.

- Ensure that all EVS personnel handling RCRA and non-RCRA pharmaceutical waste are properly trained.

- Report any hazardous pharmaceutical spills or exposures (skin or eye contact or inhalation) to their supervisors and the Safety Office.

4. Safety Office

- Conduct periodic inspections of satellite pharmaceutical waste accumulation areas during environmental rounds in order to ensure compliance with this policy and applicable regulations.

- Assist in training personnel in the handling and storage of hazardous pharmaceutical waste.

- Respond to emergency incidents involving hazardous pharmaceuticals.

- Analyze and interpret laws and regulations governing the management of hazardous pharmaceutical wastes.

- Supervise the removal, transportation, and disposal of hazardous pharmaceutical waste activities.

- Assist in reviewing and revising pharmaceutical waste policies and procedures.

V. **PROCEDURES**:

1. RCRA Hazardous Pharmaceutical Wastes

- All RCRA hazardous pharmaceutical waste (i.e. U-listed, P-listed and characteristic), except epinephrine and nitroglycerin, shall be disposed of as hazardous waste in a black waste container.

- Any materials used to clean up P-listed or U-listed hazardous pharmaceutical waste spill shall be managed as hazardous waste and be discarded in black box.

- Personal protective equipment (PPE) such as gloves and gowns that are known to be or suspected of having been contaminated with P-listed waste shall be managed as hazardous waste and be discarded in a black box.

- Unused and expired pharmaceutical shall be returned to the pharmacy. Products that have value may be returned to the suppliers.

2. Non-RCRA Hazardous Pharmaceutical Waste

- All non-RCRA hazardous pharmaceutical waste, including epinephrine salts and nitroglycerin, shall be disposed of as a medical waste. The waste is placed in a *White Container with Blue lid* labeled with the words *"For Incineration Only"* and can be stored at the satellite accumulation area up to one year or until ¾ of the container is filled.

- IV solutions that do not contain pharmaceuticals (e.g. dextrose and saline solutions with no medication additives) may be discarded outside of the waste container. If in doubt, contact the pharmacist for proper procedure.

- Unused and expired pharmaceutical shall be returned to the pharmacy. Products that have value may be returned to the suppliers.

- Personal protective equipment (PPE) that is routinely worn but does not appear to have come into contact with listed wastes may be managed as non-RCRA hazardous waste and discarded in white container with blue lid.

3. Empty Containers

- A containers that has held a ***P-listed waste*** (vials, IVs, and other containers that have held a P-listed drug) shall be managed as hazardous waste, regardless of whether or not all of the contents have been removed.

- A container that has held a U-listed waste shall be managed as non-RCRA hazardous waste if it contains no more than 3% by weight remains.

- Characteristic waste (corrosive, toxic, flammable, or reactive waste) shall be managed as non-RCRA hazardous waste if it contains no more than 3% by weight remains.

4. Other Requirements

- Disposal of any pharmaceutical waste in a drain is prohibited.

- Personal Health Information must be removed from all medication vials before being discarded.

- No sharps may be discarded in pharmaceutical waste container.

- All pharmaceutical waste containers shall be kept in the medication room or in other secured location.

5. Internal Transportation of Pharmaceutical Waste

- EVS shall pick up and transport all pharmaceutical waste containers from satellite areas to appropriate storage yard (i.e. Black container shall be transported to Hazardous Waste Yard and white, blue, and yellow chemo containers shall be transported to the Main Medical Waste Storage area).

- EVS shall **NOT** pick up any waste container that is not labeled or accumulated as indicated above. If this is discovered, the Safety Officer or Hazardous Material Specialist shall be notified to take corrective actions

- At no time shall the waste container be left unattended by EVS staff while the container is in transport to the Main Waste Storage areas.

6. WASTE MINIMIZATION

Attempts shall be made to minimize the amount or volume of pharmaceutical waste generated using one of or all of the following methods:

- **Inventory Control:** Overstocking inventory generates substantial pharmaceutical waste. Accurate material, product, and waste tracking improve material handling and storage procedures. Using inventory on a first-in/first-out basis minimizes waste from expired chemicals. Some suppliers will take back expired pharmaceuticals.

- **Spill Prevention:** Spill and leak prevention are critical to waste minimization. Methods of reducing or preventing spills include: transporting liquid pharmaceuticals in secondary containment and maintaining the physical integrity of containers.

- **Delivering Chemo drugs:** Deliver chemotherapy drugs in ziplock bags to the nursing units in hard plastic trays or closed "coolers." This will provide greater spill and leak protection during transport.

- **Waste Stream Segregation:** Segregate hazardous materials from nonhazardous materials; sort hazardous waste by contaminant; and separate liquid from solid waste. This segregation reduces waste haulage volumes, simplifies disposal, and facilitates recovery and recycle. Do not mix RCRA waste with non-RCRA waste.

- **Reverse Distribution:** Return unwanted medications directly to the pharmaceutical manufacturer

- **Automated Dispensing Cabinets:** The "Just-in-Time" medication storage process on the units can result in fewer returns to Pharmacy.

- **Considering Lifecycle Impacts in the Purchasing Process:** Examples include but are not limited to: Specifying that you will not accept any drugs with less than one year dating unless they are only available with shorter expiration dates, selecting products with less packaging especially if drug contains a P-listed constituent of concern, considering single dos single dose containers

VI. REFERENCES

1. 40 Code of Federal Regulations (CFR) 261.3

2. Division 4.5, 22 California Code of Regulations (CCR).

3. Joint Commission Standard EC.02.02.01 and MM.01.01.03

NOTED AND APPROVED:

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Cynthia M. Oliver, Chief Executive Officer Date

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Ellen Rothman, M.D., Chief Medical Officer Date

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Lessie Barber, R.N., Nursing Director Date

Signature(s) on File.

TABLE 1

RCRA Hazardous Pharmaceuticals - Waste that contains the sole active ingredient of the “P” or “U” listed waste (**Table 1 and Table 2**) or exhibits at least one of the characteristics (ignitability, toxicity, corrosivity, and reactivity).

- **P-Listed Pharmaceutical –** P-listed waste are commercial chemical products that are categorized as acutely toxic. One of the primary criteria for including a drug on the P-list as acutely hazardous is an oral lethal dose of 50 mg/kg (LD50) or less. LD50 is the amount of a material, given all at once, which causes the death of 50% of a group of test animals. Eight chemicals on the P-list are used as pharmaceuticals. Generator can’t accumulate more than one quart of P-listed waste at satellite accumulation area. The two most commonly generated P-listed chemicals in healthcare facilities are **epinephrine and nitroglycerin**. Fortunately both are excluded by both federal and state.

- **U-Listed Pharmaceutical –** Chemicals that may be toxic to human, and may also include chemicals that display other characteristics, such as ignitability or reactivity

- **Ignitability (Table 3) -** Aqueous solution containing drug formulation containing 24% or more alcohol by volume, having a flashpoint less than 140° F or 60° C, Non-aqueous solutions with flash points < 140° F, oxidizers, and flammable aerosol. Examples: Rubbing alcohol, topical preparation, clindamycin, some injections: Paclitaxel.

- **Toxicity (Table 4)** – Pharmaceutical that contain heavy metals such as arsenic, barium, cadmium, and mercury above regulatory level in mg/L

- **Corrosivity** – pH less than or equal to 2 or greater than or equal to 12.5-Hazardous waste (Examples Glacial Acetic Acid, Sodium Hydroxide, Potassium Hydroxide (alkaline), Trichloracetic Acid (acid), Expired/unused silver nitrate(oxidizer)

- **Reactivity** – Unstable under normal condition (e.g. water reactive, air reactive). Reactive wastes are unstable under "normal" conditions. They can cause explosions, toxic fumes, gases, or vapors when heated, compressed, or mixed

with water. ***Nitroglycerin is the only drug that is potentially reactive***. However, Nitroglycerin is excluded both by Federal and California

P-LISTED PHARMACEUTICAL

CONSTITUENT OF CONCERN	WASTE CODE	COMMENTS
Arsenic trioxide	P012	Chemotherapy agent
Epinephrine base	P042	
Nicotine	P075	
Nitroglycerin	P081	Excluded or exempted
Phentermine (CIV)	P046	
Physostigmine	P204	
Physostigmine salicylate	P188	
Warfarin >0.3%	P001	

NOTE: Epinephrine salt is exempted

TABLE 2
U-LISTED PHARMACEUTICAL

CONSTITUENT OF CONCERN	WASTE CODE	COMMENTS
Chloral hydrate (CIV)	U034	
Chlorambucil	U035	Chemotherapy Agent
Cyclophosphamide	U058	Chemotherapy Agent
Daunomycin	U059	Chemotherapy Agent
Dichlorodifluoromethane	U075	
Diethylstilbestrol	U089	Chemotherapy Agent
Hexachlorophene	U132	
Lindane	U129	
Melphalan	U150	Chemotherapy Agent
Mercury	U151	
Mitomycin C	U010	Chemotherapy Agent
Paraldehyde (CIV)	U182	
Phenol	U188	
Reserpine	U200	
Resorcinol	U201	
Saccharin	U202	

Selenium sulfide	U205	
Streptozotocin	U206	Chemotherapy Agent
Trichloromonofluromethane	U121	
Uracil mustard	**U237**	Chemotherapy Agent
Warfarin <0.3%)	U248	

Table 3
Pharmaceuticals with Ignitability Characteristics (D001)

IGNITABLE PROPERTIES	RESOURCES	IGNITABLE DRUG FORMULATIONS
Aqueous drug formulation containing 24 % or more alcohol by volume and having a flashpoint of less than 140 º F or 60 º C (261.21(a)(1))	Safety Data Sheet	Erythromycin Gel 2%
Liquid drug formulations, other than aqueous solutions containing less than 24 percent alcohol, with a flashpoint of less than 140 degrees F or 60 degrees C	Safety Data Sheet	Flexible collodion used as a base in wart removers is not an aqueous solution and has a flashpoint = 45 degrees C
Flammable aerosol propellants meeting the DOT definition of compressed gas (261.21(a)(3))	Safety Data Sheet	Primatene aerosol
Oxidizers or materials that readily supply oxygen to a reaction in the absence of air as defined by the DOT	Safety Data Sheet	Potassium permanganate

TABL 4 - TOXICITY

INGREDIENT	WASTE CODE	REGULATORY LEVEL (mg/l)	DRUGS FORMULATIONS CONTAINING THESE INGREDIENTS
Arsenic	D004	5.0	Arsenic trioxide (also P-listed)
Barium	D005	100.0	Barium sulfate (used in radiology)

Silver	D011	5.0	Silver sulfadiazine cream