



Policy Number	OHS.PHARM.021
Date of Issue	January 2013
Review Dates	August 15, 2018, January 16, 2019
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Policy Owner(s)	Pharmacy

Regulated/RCRA Pharmaceutical Waste Disposal

I. Purpose

The purpose of the policy is to:

- A. Provide a framework for development of a safe, efficient and environmentally sound pharmaceutical waste management policy;
- B. Ensure that every effort is made to minimize the generation of regulated pharmaceutical waste;
- C. Ensure that all pharmaceutical waste is managed and disposed of in accordance with applicable Environmental Protection Agency (EPA) regulations, US Department of Transportation (DOT regulations), Occupational Safety & Health Administration (OSHA) regulations as well as the State and local regulations.

II. Scope

This policy applies to (i) Ochsner Health (OH), (ii) Ochsner Clinic Foundation, and/or (iii) all facilities and entities wholly owned and/or leased by Ochsner Clinic Foundation (“Ochsner”).

III. Definitions

Regulated Pharmaceutical Waste is medication waste that is harmful to the environment and the disposal of which is regulated by environmental laws of the state and federal government. This waste can also be referred to as Resource Conservation and Recovery Act (RCRA) waste or hazardous waste. The use of “Hazardous” in this policy will refer to hazardous waste as defined by RCRA, not by National Institute for Occupational Safety and Health (NIOSH).

- A. **RCRA**- U.S. federal law authorizing the U.S. Environmental Protection Agency (“EPA”) to administer regulations governing management and disposal of hazardous wastes [40 CFR section 261.4(a)].
- B. **RCRA Listed Hazardous Waste**-The four types of RCRA “listed” waste are F, K, P, and U, with a three-digit identifier (e.g., F005, P039, U135)
 1. “F” listed, or non-specific-source wastes that are material-specific, such as solvents, generated by several industries. Waste codes range from F001-F039.
 2. “K” listed, or source specific wastes from specific sectors of industries and range from K001 to K181.
 3. “P” listed (acutely hazardous waste) or discarded commercial chemical products including off-specification products, container residuals, spill residue runoff, off specification species, or active ingredients that have spilled or are unused and that have been, or are intended to be, discarded.

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Waste codes range from P001 to P205. For these acutely hazardous wastes, as little as 2.2 pounds of these wastes generated in a given calendar month designates a facility as a large quantity generator.

4. "U" listed or discarded commercial chemical products including off-specification products, container residuals, spill residue runoff, off-specification species, or active ingredients that have spilled or are unused and that have been or are intended to be discarded. Waste Codes range from U001-U411.
- C. **RCRA Characteristic Hazardous Waste**- Waste that displays one of the four hazardous characteristics specified in EPA RCRA regulations:
1. Ignitability- a waste that creates fires under certain conditions, is spontaneously combustible, and has a flash point of less than 140 degrees Fahrenheit, is an ignitable compressed gas, or is an oxidizer. The waste code is D001.
 2. Corrosive- a waste that is an acid or base that is aqueous and has a pH less than or equal to 2, or greater than or equal to 12.5; or a liquid capable of corroding metal containers. The waste code is D002.
 3. Reactivity- a waste that is unstable under normal conditions. A reactive waste can cause an explosion, toxic fumes, gases, or vapors when mixed with water. The waste code is D003.
 4. Toxicity- a waste that is harmful or fatal when ingested or absorbed. When toxicity characteristic wastes are disposed of on land, contaminated rain or liquid may drain (leach) from the waste and pollute ground water. The waste codes range from D004 to D043.
- D. **Central Accumulation Area (CAA)**- Area of facility designated for accumulation and preparation of facility regulated/RCRA waste for pickup by waste vendor.
- E. **Satellite Accumulation Area (SAC)**- Area designated for pharmaceutical waste collection and temporary accumulation of full waste bins waiting pickup; 1) at or near the point of waste generation, 2) under control of the waste generator, 3) segregated from other pharmaceutical storage, and 4) labeled per regulations
- F. **Hazardous Pharmaceutical Waste**- As defined by the federal EPA Resource Conservation and Recovery Act, hazardous pharmaceutical waste is any drug waste that exhibits any of the RCRA defined characteristics or contains chemical that would render it hazardous.

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- G. **Rx Waste Characterization List-** A list built by contracted waste vendor of pharmaceuticals used/stored/available in the pharmacy by generic name and NDC that includes appropriate waste type and 3-digit identifier (D002, F001 etc.) and other information necessary for identification, segregation, packing and labeling of regulated/RCRA pharmaceutical waste and non-regulate pharmaceutical waste.

IV. Policy

All pharmaceutical waste shall be disposed of in accordance with all local, state, and federal regulations and in coordination with OH contracted waste management vendors. Controlled substances are not included in this policy.

V. Accountability and Responsibilities

As defined by state and federal environmental regulations, pharmacy is the source, or generator, of all pharmaceutical waste. Pharmacy will collaborate with the department at their site with oversight of the hazardous waste program to assist in maintaining compliance.

VI. Procedures/Standards and Roles –

A. Hiring & Training

1. The job description used in hiring all positions that could possibly come in contact with or handle regulated/RCRA pharmaceutical waste shall include wording to inform the applicant of the potential exposure risks.
2. Personnel involved in hazardous waste management and emergency response actions shall receive RCRA Hazardous Waste training annually. Employees completing training shall have documentation of completion. *(Note: Handling and administration of medications with RCRA characteristics is not considered waste management. Waste management occurs following disposal of medications with RCRA characteristics.)*
3. Regulated/RCRA waste disposal guidance shall be available to pharmacy, nursing and EVS personnel.
4. Emergency response training for hazardous drug/chemical spills shall be required for positions tasked with cleanup responsibilities.

B. Documentation and reports

1. Rx Waste Characterization List-medications approved for Formulary, shall be assigned a proper waste code and added to the Rx Characterization list by

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the waste vendor. Rx Characterization list will be provided to IS for inclusion of the pharmaceutical waste bin code on the medication administration record.

2. P” Listed Waste report -A monthly report shall be created and logged by pharmacy leadership at each pharmacy as to quantity of “P” listed waste dispensed. Report is built in the Electronic Health Record. Log shall be on file in pharmacy for a minimum of 3 years.
3. Inspection of Satellite Accumulation Area (SAA) -Weekly inspection of pharmacy’s SAA shall include status of area, concerns, report of concerns to pharmacy leadership, action plan and results. Inspections shall be kept on file in the pharmacy for a minimum of 3 years. Responsible party shall be assigned by pharmacy leadership.
4. As required by generator status, a notification of hazardous waste activity will be provided to the state by the department with responsibility for regulated/RCRA waste disposal in each facility (EVS, Safety, Facility, etc.).
5. Waste Manifests- A multi-page document with a unique number that is completed and signed by the generator, carrier, and the receiver or final destination facility that provides a description of the cargo. Waste manifests shall be the responsibility of the waste vendor and facility department with responsibility for regulated/RCRA waste disposal in each facility (EVS, Safety, Facility etc.) If the pharmacy receives any wasted manifests, pharmacy will send to department responsible for regulated/RCRA waste in the facility.
6. Pharmaceutical (Rx) Profile - An annual form based on inventory created by waste vendor. Profiles shall be signed and returned to the waste vendor by the department with responsibility for regulated/RCRA waste disposal in each facility (EVS, Safety, Facility etc.) or signed by the waste vendor on behalf of OH.

C. Waste Bin Designation- Regulated/RCRA pharmaceutical waste shall be assigned the following code to designate the appropriate bin for disposal. The waste bin designation codes shall appear on the MAR under references in the electronic medical record. Medications without a waste code shall be disposed of in **BLUE** pharmaceutical waste bins, with the exception of off-site provider-based clinics, freestanding emergency departments, applicable critical access hospitals and

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home infusion facilities which may use only black pharmaceutical waste bins. Facility based (on-site) clinics may use bins in the same manner as inpatient.

1. **BKC** –Dispose in appropriately labeled BLACK BKC bin.
2. **PBKC** –Dispose of package/wrapper or medication in appropriately labeled BLACK PBKC bin. Off-site clinics do not return pharmaceutical waste to pharmacy. **Arsenic Trioxide (Trisenox) vials, iv bags, tubing, syringes and other materials used in preparation and administration shall be disposed of as *segregated* “PBKC” listed waste in 2 or 8-gallon black waste bins. Under no circumstances can arsenic trioxide be combined with other hazardous waste.
3. **SP**-Place the aerosol/inhaler in a zipper sealed bag and send to the pharmacy for disposal in appropriately labeled BLACK bin or directly in appropriately labeled BLACK bin if located near patient care areas . Off-site locations do not return pharmaceutical waste to pharmacy.
4. **SPC**-Place corrosive in zipper sealed bag and send to pharmacy for disposal in appropriately labeled BLACK SPC bin. Off-site locations do not return pharmaceutical waste to pharmacy.
5. **SPO**- Place oxidizer in a zipper sealed bag and send to pharmacy for disposal in appropriately labeled BLACK SPO bin. Off-site locations do not return pharmaceutical waste to pharmacy.
6. **SPLP**- Place SPLP waste in a zipper sealed bag and send to pharmacy for disposal in appropriately labeled BLACK SPLP bin. Off-site locations do not return pharmaceutical waste to pharmacy.
7. **CHEMO**- Place chemo waste in either a YELLOW trace chemo bin or a BLACK (BKC) bin for “Bulk” chemo waste.
 - a. BLACK (BKC) bin shall be utilized for chemotherapy waste with residual of 3% or more drug remaining. All chemotherapy is considered regulated/RCRA by EPA/RCRA and USP 800 regulations. Waste vendor picks up.
 - b. **Yellow “Trace Chemo”** bins are ordered through Lawson. Packages containing less than 3% of the pharmaceutical shall be considered “empty”, Yellow containers shall be used for “empty” chemotherapy vials, IV bags, syringes, along with any material used during the preparation, administration and handling of the chemotherapy, including all personal protective equipment (PPE).

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D. Pharmaceutical Waste Bins

1. All staff shall have responsibility for proper use of bins.
2. General trash should not be disposed of in the waste bins.
3. All bins shall be labeled with start date and RCRA waste codes. Waste vendor employee shall be responsible for labeling. Unlabeled bins shall not be used.
4. Satellite Accumulation Areas throughout facilities shall have designated locations. Emergency contact phone number shall be available above or near the hazardous pharmaceutical waste satellite accumulation area.
5. Waste vendor employees shall pick up all accumulated bins, with the exception of yellow trace chemo bins, and transport to facility Central Accumulation Area.
6. Waste vendor employees shall clean, label and return permanent bins to each location.
7. Yellow trace chemo bins shall be picked up by facility department with responsibility for biohazard waste in each facility (EVS, Safety, Facility etc.) for transport to Central Accumulation Area
8. Bin lids shall remain closed except when waste is being added.
9. Full bins shall be stored in the Satellite Accumulation Area until picked up by waste vendor or the department with responsibility for regulated/RCRA waste in each facility.
10. All regulated/RCRA pharmacy waste shall have bins meeting the requirement for secondary containment in the SAA and CAA.

E. Disposal Determination

1. Non-chemo medication packages containing less than 3% of the pharmaceutical shall be considered "empty" and shall be disposed of in regular trash bins or BLUE nonregulated Rx waste bins.
2. Empty sharps shall be disposed of in RED sharps bins.
3. Drain disposal shall be permitted for IV solutions containing plain saline solution, dextrose solution, lactated ringers, and nutrients such as vitamins and added salts such as potassium chloride and/or other electrolytes.
4. Medications and/or medication containers (vials, ampoules, cups, IV bags) with 3% or more than 3% medication remaining shall be disposed of in pharmaceutical waste bins indicated in section C above.
5. Sharps with medication shall be disposed of in a BLACK sharps bin.

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6. Free flowing liquids or pharmaceutical packages with the potential to leak shall be placed in a zipper sealed bag prior to disposal in designated pharmaceutical waste bin.

F. Supplies of Bins within a Facility

1. Hospital pharmacies, chemo infusion areas, nursing units, outpatient departments and on-site ambulatory clinics shall be supplied with blue and black bins by system waste vendor.
2. All hospital pharmacies, chemo infusion areas, nursing units, outpatient departments, and on-site ambulatory clinic's yellow "trace" chemo bins and bags shall be supplied through PAR with Materials Management or ordered through Lawson.
3. Off-site chemo infusion centers shall be supplied with bins through Lawson. The department or vendor with responsibility for regulated/RCRA waste in each facility shall be contacted for pick up and transport of bins to facility storage area.
4. Provider based clinics and freestanding emergency departments shall order Black pharmaceutical waste bins through Lawson. The department or vendor with responsibility for regulated/RCRA Waste in each facility (EVS, Safety, Facility etc.) shall be contacted to pick up and transport bins to facility storage area.
5. Some off-site provider-based clinics and freestanding emergency departments may need to obtain approval from the manager or building director before scheduling a pharmaceutical waste truck from the waste vendor for removal of pharmaceutical waste.
6. A waste vendor technician shall provide The Gayle and Tom Benson Cancer Center, North Campus, Jefferson Highway clinics and atrium towers, Clearview Medical Complex, Covington Medical Complex, and St. Tammany Cancer Center with the black pharmaceutical bin and shall pick up and exchange bins. The department or vendor with responsibility for regulated/RCRA waste in each facility may be contacted for pickup or exchange of bins between visits by the waste vendor technician.
7. All Clinics that use Botox shall order black two-gallon bins from Lawson for disposal.



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8. Hospitals and clinics serviced by the waste vendor technician shall have facility pickups scheduled by the technician for removal of pharmaceutical waste.
9. The pharmaceutical waste manifest must be signed by a DOT trained OH personnel from the department with responsibility for Regulated/RCRA Waste (EVS, Safety, Facility etc.).

VII. Enforcement and Exceptions

There shall be no exceptions to the policy.

VIII. Internal References

- A. OHS.PHARM.043 - Hazardous Drugs
- B. OHS.QUAL.006 - Hazard Communication Program
- C. RCRA Waste Minimization Plan (site specific)
- D. OHS.SAFE.OS.040 - Hazardous Drug/Chemical Spill Response Team

IX. External References

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X. Attachments

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XI. Policy History

Former Policy - Policy Title #

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Reviewer	Date of Review	Notes
<i>System Operations Subcommittee</i>	<i>10/24/23</i>	<i>Approved</i>
<i>Pharmacy Leadership Policy Committee</i>	<i>11/9/23</i>	<i>Approved</i>
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