



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

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## Regulated/RCRA Pharmaceutical Waste Disposal

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### 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 of Louisiana (LADEQ) and local regulations.

### II. Scope

This policy applies to (a) Ochsner Health System (OHS), (b) Ochsner Clinic Foundation, and/or (c) 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 RCRA waste or hazardous waste. The use of the word "hazardous" is discouraged due to confusion with USP 800 Hazardous Drugs as defined by NIOSH. The use of "Hazardous" in this policy is limited to its use in specific regulatory statements.

- A. **RCRA**-Resource Conservation and Recovery Act which defines Listed Hazardous Waste and Characteristic Hazardous Waste.
- 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 specifically identified industries and range from K001 to K161.
  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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---

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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, or one quart of these wastes stored in a satellite accumulation area 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- Area of facility designated for accumulation and preparation of facility regulated/RCRA waste for pickup by waste vendor.
- E. Satellite Accumulation Area- Area designated for pharmaceutical waste collection and temporary accumulation of full waste containers 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 solid drug waste that exhibits any of the RCRA defined characteristics of hazardous waste or is RCRA listed or is an Industry Dangerous Drug.



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---

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---

- G. Industry Dangerous Drugs-Chemicals/drugs not yet evaluated by the EPA per RCRA definition of hazardous but identified as dangerous to human health or the environment by ASHP, NIOSH and OSHA.
- H. NIOSH-National Institute for Occupational Safety and Health
- I. OSHA-Occupational Safety and Health Administration
- J. ASHP- American Society of Health-System Pharmacists
- K. 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 ,non-regulate pharmaceutical waste and industry designated "dangerous drugs" per NIOSH, OSHA and ASHP guidelines.

#### IV. Policy

All pharmaceutical waste shall be disposed of in accordance with all local, state, and federal regulations and in coordination with OHS 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 within OHS and as such, shall have the ultimate accountability for oversight of compliance.

- A. The pharmacy directors (DOP) shall have the accountability to maintain compliance within each facility, overseeing all responsibilities defined below.
- B. Responsibilities may be assigned to staff, facility environmental services or contracted environmental services.
- C. System Pharmacy Administration shall monitor all 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. Training for safe handling and personal protection shall occur at orientation and annually for all employees with documentation kept in OLN (Ochsner online learning network).



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---

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---

- a. RCRA Working Knowledge training shall be required of one designated person in each facility pharmacy, nursing management and EVS annually
  - b. All pharmacy, nursing and EVS personnel handling regulated/RCRA waste shall receive RCRA Awareness training.
  - c. Oversight of training and documentation shall be assigned to a designated person in each department.
  - d. Specific handling (procedural) training shall be required for pharmacy, nursing, and EVS positions with regulated/RCRA pharmaceutical waste responsibilities.
  - e. Emergency Response training shall be required for positions tasked with cleanup responsibilities.
3. All employees shall sign an Attestation acknowledging their completed training, understanding of use of personal protective equipment (PPE) and understanding of risks arising from improper handling or lack of adherence to the policy.
- B. Documentation and reporting**
1. Rx Waste Characterization List-all pharmaceuticals brought into any facility shall be identified, assigned the proper waste code and added to the Rx Characterization list:
    - a. Additions to the formulary shall be sent by IS to the contracted vendor quarterly.
    - b. Non-formulary pharmaceuticals shall be sent by IS to the contracted vendor quarterly.
    - c. Pharmaceutical Waste Bin Codes shall be identified by System Clinical Pharmacy team during due diligence process for each medication and given to IS for inclusion in the EPIC drug profile created.
    - d. Waste Vendor shall supply the Master Rx Waste Characterization list to the pharmacies annually on or about January 1.
    - e. A current copy of the Rx Waste Characterization list shall be available in every pharmacy and on Formweb for reference.
  2. "P" Listed Waste report (Louisiana regulation)-monthly report shall be created and logged by DOP at each pharmacy as to quantity of "P" listed waste

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## Regulated/RCRA Pharmaceutical Waste Disposal

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- dispensed. Report is built in EPIC. Log shall be on file in pharmacy for a minimum of 3 years.
3. Inspection of Satellite Accumulation Area (Federal and LA)-Weekly inspection of SAA shall include status of area, concerns, report of concerns to DOP, 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 each DOP.
  4. HW-1 (Federal and LA) update shall be the responsibility of the department with responsibility for regulated/RCRA waste disposal in each facility (EVS, Safety, Facility, etc.).
  5. Waste Manifests (Federal and LA) 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 manifests, pharmacy shall send immediately to department responsible for regulated/RCRA waste in the facility.
  6. Pharmaceutical (Rx) Profile (Federal and LA)-annual form based on inventory created by waste vendor. Each DOP shall sign and send to the waste vendor and the department with responsibility for regulated/RCRA waste disposal in each facility (EVS, Safety, Facility etc.).
- C. **Waste Bin Designation**-Regulated/RCRA pharmaceutical waste shall be assigned the following code to designate the appropriate container for disposal. The waste bin designation codes shall appear on the MAR under references in the EPIC system, in Pyxis and shall appear on the medication labels printed by pharmacy.
1. Medications without a waste code shall be disposed of in a **BLUE** pharmaceutical waste container, with the exception of off-site provider-based clinics and freestanding emergency departments which shall use only black pharmaceutical waste containers. Facility based (on-site) clinics may use containers in the same manner as inpatient.
  2. **BKC** –Nurse shall dispose in appropriately labeled BLACK BKC container
  3. **PBKC** –Nurse shall place package/wrapper or medication in a zipper sealed bag then dispose in appropriately labeled BLACK PBKC container in facilities where PBKC container is available-until available, nurse shall send bag back to the pharmacy for disposal. 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



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---

## Regulated/RCRA Pharmaceutical Waste Disposal

---

disposed of as *segregated* "PBKC" listed waste in 8-gallon black waste containers and labels supplied by Stericycle. Under no circumstances can arsenic trioxide be combined with other hazardous waste.\*\*

4. **SP-Nurse** shall place the aerosol/inhaler in a zipper sealed bag and send to the pharmacy for disposal in appropriately labeled BLACK container. Off-site locations do not return pharmaceutical waste to pharmacy.
  5. **SPC-Nurse** shall place corrosive in zipper sealed bag and send to pharmacy for disposal in appropriately labeled BLACK SPC container. Off-site locations do not return pharmaceutical waste to pharmacy.
  6. **SPO-Nurse** shall place oxidizer in a zipper sealed bag and send to pharmacy for disposal in appropriately labeled BLACK SPO container. Off-site locations do not return pharmaceutical waste to pharmacy.
  7. **SPLP-Nurse** shall place SPLP waste in a zipper sealed bag and send to pharmacy for disposal in appropriately labeled BLACK SPLP container. Off-site locations do not return pharmaceutical waste to pharmacy.
  8. **CHEMO-Nurse/pharmacy** shall place chemo waste in either a YELLOW trace chemo container or a BLACK "Bulk" chemo waste container
    - a. BLACK container labeled for **BULK CHEMO** waste 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** containers are ordered through Lawson and picked up by the vendor or the department with responsibility for biohazard waste in each facility (along with regulated medical waste, red sharps, and nonregulated Rx waste). 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).
- D. Container Handling**
1. All staff shall have responsibility for proper use of containers.
  2. No general trash shall be disposed of in the waste containers or red bag
  3. All containers shall be labeled with start date, RCRA waste codes and date container is deemed full. Waste vendor employee shall be responsible for labeling. Unlabeled containers shall not be used.



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---

4. Containers used throughout facilities shall have designated locations, marked with tape on floor and a sign "Hazardous Pharmaceutical Waste Area" with the 24hour emergency phone number for the facility.
  5. Waste vendor employees shall pick up all accumulated containers, with the exception of yellow trace chemo containers, and transport to facility Central Accumulation Area.
  6. Waste vendor employees shall clean, label and return permanent containers to each location.
  7. Yellow trace chemical containers 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. Container lids shall remain closed except when waste is being added.
  9. Full containers shall be stored in the Satellite Storage Area until picked up by waste vendor or the department with responsibility for regulated/RCRA waste in each facility.
  10. Satellite Storage Area shall be clearly marked, separated from other pharmaceutical storage and have signage saying, "Hazardous Pharmaceutical Waste" and the 24-hour emergency phone # for facility.
  11. All regulated/RCRA pharmacy waste shall have containers meeting the requirement for secondary containment in the SAA and CAA (drums)
- 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 containers or BLUE nonregulated Rx waste containers.
  2. Empty sharps shall be disposed of in RED sharps containers.
  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.
    - a. Any materials poured down the drain shall have a profile that allows this and shall have adequate rinse to prevent accumulative contamination.
  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 containers indicated in C above.



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---

5. Sharps with medication shall be disposed of in a BLACK 2-gallon sharps container.
  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 container.
- F. Supplies of Containers 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 containers by system waste vendor.
  2. All hospital pharmacies, chemo infusion areas, nursing units, outpatient departments, and on-site ambulatory clinics yellow "trace" chemo containers and bags shall be supplied through PAR with Materials Management or ordered through Lawson.
  3. Off-site chemo infusion centers shall be supplied with containers through Lawson. The department or vendor with responsibility for regulated/RCRA waste in each facility shall be contacted for pick up and transport of containers to facility storage area.
  4. Provider based clinics and freestanding emergency departments shall order Black pharmaceutical waste containers 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 containers to facility storage area.
  5. Some off-site provider-based clinics and freestanding emergency departments may need 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, and Jefferson Highway clinics and atrium towers with the black pharmaceutical container and shall pick up and exchange containers. The department or vendor with responsibility for regulated/RCRA waste in each facility may be contacted for pickup or exchange of containers between visits by the waste vendor technician.
  7. All Clinics that use Botox shall order black two-gallon containers from Lawson for disposal. The clinic shall obtain SPLP stickers from the waste vendor technician for labeling the containers.





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---

## Regulated/RCRA Pharmaceutical Waste 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 shall be signed by a DOT trained Ochsner Health System department with responsibility for Regulated/RCRA Waste in each facility (EVS, Safety, Facility etc).
- G. Emergency Spill Plan**
1. Spills of pharmaceutical or Chemo waste shall be cleaned up immediately by trained department staff.
  2. Spills shall be reported in the Ochsner Incident Reporting System.
  3. EVS shall be called to assist and for final clean if the spill is larger than 1 liter in a patient care area.
  4. Spill Reports shall be reviewed and analyzed by pharmacy, nursing and EVS administration for improvement opportunities.
  5. Spill response, safety and communication equipment shall be tested annually and maintained as required by all state and federal regulations.
  6. Emergency Contact list shall be placed next to the phone designated to be used in the event of an emergency in the pharmaceutical waste satellite accumulation area. Contact information shall be kept current and include, but not limited to:
    - a. Pharmacy Director
    - b. Pharmacy Designated Employee
    - c. Hospital Emergency Coordinator
    - d. Fire Department
    - e. Police
    - f. Emergency Medical Service
    - g. EPA
- H. Compliance Inspection/Audit**
1. Routine inspections/audits of staff performance/compliance shall be performed and documented by leadership of the department.
  2. Inspection/audit reports shall be retained on file in the department for a minimum of 3 years.
- I. Annual Waste Minimization Review**
1. Pharmacy shall work with the department with responsibility for pharmaceutical waste in each facility (EVS, Safety, Facility etc.) annually to



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---

## Regulated/RCRA Pharmaceutical Waste Disposal

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complete a review of regulated/RCRA pharmaceutical waste produced to determine areas where volume of waste can be reduced.

2. An annual inventory is sent to Facility management for “Right to Know” reporting purposes to the State and Local Authorities.
3. A waste minimization goal and program shall be implemented in all the pharmacies and updated annually for each facility.

### VII. Enforcement and Exceptions

There shall be no exceptions to the policy.

### VIII. Internal References

- A. OHS.PHARM.043 Hazardous Drug Handling
- B. OHS.SAFESEC.015 Hazardous Materials Training and Material Safety Data Sheet
- C. OHS.SAFESEC.006 Hazardous Materials and Waste Management
- D. OMC.FHC.001 Waste Minimization Plan

### IX. External References

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### X. Attachments

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### XI. Policy History

Former Policy - Policy Title #

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### XII. Approved

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Warner Thomas, President and Chief Executive Officer

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Pete November, Executive Vice President and  
Chief Administrative Officer



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

---

## Regulated/RCRA Pharmaceutical Waste Disposal

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### Reviewers (if applicable)

Debbie Simonson, VP System Pharmacy, XX/XX/2018  
Chief Nursing Officer Council, XX/XX/2018  
System Pharmacy and Therapeutics Committee XX/XX/2018  
OMC- Therapeutics Committee, XX/XX/2018  
OMC- Medical Staff Operating Committee, X/XX/2018  
OMC – West Bank- Therapeutics Committee, X/XX/2018  
OMC – West Bank- Medical Staff Operating Committee, X/XX/2018  
Ochsner Baptist Medical Center- Therapeutics Committee, X/XX/2018  
Ochsner Baptist Medical Center- Medical Staff Operating Committee, X/XX/2018  
Staff Executive Committee, X/XX/2018  
Medical Advisory Committee, X/XX/2018  
OMC – Baton Rouge- Therapeutics Committee, X/XX/2018  
Medical Executive Committee, OMC – Baton Rouge, X/XX/2018  
OMC- Kenner- Therapeutics Committee, X/XX/2018  
Medical Executive Committee, OMC – Kenner, X/XX/2018  
OMC- North Shore Therapeutics Committee, X/XX/2018  
OMC- North Shore Medical Executive Committee, X/XX/2018  
Ochsner St. Anne Hospital- Therapeutics Committee, X/XX/2018  
Ochsner St. Anne Hospital- Medical Executive Committee, X/XX/2018  
System Policy Review Committee, X/XX/2018