



# Hazardous Waste Pharmaceuticals An Update from EPA

Office of Resource Conservation & Recovery  
Lisa Lauer, Jessica Young, Kristin Fitzgerald



# Update on ORCR's Pharmaceutical Work

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1. Update on Management Standards for HW Pharmaceuticals from healthcare facilities Proposal
2. Updating EPA's Website to make it clear we're working on a proposal
3. Inspector General report on outdated hazardous waste listings for pharmaceuticals
4. Drug Enforcement Administration proposed rule for ultimate user (consumer) disposal of controlled substances
5. ORCR developing a Wiki for healthcare professionals to share HW pharmaceutical know-how
6. NEWMOA letter to ORCR Office Director
7. Environmental Science and Technology article about lifecycle analysis of consumer pharmaceutical disposal
8. Resources for the healthcare sector

# 1. Update on Pharmaceuticals Proposed Rule

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- ▶ EPA proposed to add hazardous waste pharmaceuticals to the Federal universal waste program in December 2008
- ▶ In response to commenters' concerns, especially about the proposal's lack of notification and tracking requirements for the handling and shipment of hazardous waste pharmaceuticals, the Agency has decided not to finalize the addition of HW pharmaceuticals to the universal waste program
- ▶ EPA is moving forward with a new proposal for healthcare facility-specific regulations for the management of hazardous waste pharmaceuticals
  - ▶ Will address comments on the UW proposal
  - ▶ Will provide a regulatory scheme to address the unique issues that healthcare facilities face
  - ▶ Direct continuation of the previous proposal
- ▶ The new proposal is anticipated to be published and available for public comment in March 2013
  - ▶ Already passed two key internal milestones and are working toward the final internal milestone before the proposal gets passed to OMB

# Updates 2, 3, and 4 on Pharmaceuticals

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2. We will be updating EPA's HW pharmaceutical webpage in an attempt to make it clear that the current rulemaking is a continuation of the previous efforts
  - ▶ Plan to move it out of the UW section into the generator section of our website
  - ▶ Plan to include resource section to webpage including link to "10-step blueprint"
3. EPA Inspector General report on outdated HW listings for pharmaceuticals
  - ▶ Investigation occurred during Summer/Fall of 2011 (centered on our office)
  - ▶ Final report out May 29, 2012 available at [www.epa.gov/oig](http://www.epa.gov/oig)
  - ▶ Our office is working on a second response due in 90 days
4. DEA proposal to provide disposal options for consumers' controlled substances (ultimate users) at OMB
  - ▶ Background: Congress directed DEA to draft regulation to provide consumers with more disposal options for controlled substances
  - ▶ ORCR, OW, OAQPS, ORD, OCSPP, R5, and R3 all commented on the proposal during interagency review
  - ▶ Requested a call with DEA to ask clarifying questions
  - ▶ If you're interested in commenting, keep an eye out for the proposal (potentially out in August- OMB started its review 5/15/12)

# Update 5 on Pharmaceuticals

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## 5. COMING SOON....Wiki for Healthcare Sector

- ▶ Healthcare facilities often struggle with determining which drugs in its formulary of thousands of drugs are hazardous waste?
- ▶ EPA will be hosting a platform for the healthcare sector to share its expertise with other members of the healthcare sector on which drugs are hazardous wastes
  - ▶ Similar in concept to wikipedia but with more controls
- ▶ Anyone will be able to view the material in the wiki
- ▶ Upon request, members of the healthcare community, regulators, etc., will be able to contribute and/or edit the material in the wiki
- ▶ The wiki will be fully searchable by drug name, brand name, waste code, etc.
- ▶ Expect to launch late summer 2012

# Updates 6 and 7 on Pharmaceuticals

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## 6. NEWMOA letter to EPA (February 2012)

- ▶ NEWMOA is concerned that EPA's rulemaking is not addressing all of the issues that surround pharmaceutical waste, especially the waste pharmaceuticals that are not considered hazardous waste
- ▶ NEWMOA suggests an extended producer responsibility (EPR) system approach
- ▶ EPA is in the process of responding to the letter

## 7. American Environmental Science and Technology (ES&T) journal article with a lifecycle analysis of pharms disposal

- ▶ Journal article recommends trash disposal over take backs for household pharms based on greenhouse gas emissions for take-backs
- ▶ ORD prepared a comment submission to ES&T which ORCR and OW co-reviewed

## 8. Resources for the Healthcare Sector

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- ▶ **EPA memos/letters**
  - ▶ Guidance for the management of P-listed containers (RCRAOnline # 14827)
  - ▶ Phentermine salts clarification (RCRAOnline # 14831)
  - ▶ Epinephrine salts clarification (RCRAOnline # 14778)
  - ▶ Residues within syringes (RCRAOnline # 14788)
  
- ▶ **Healthcare Environmental Resource Center (HERC)**
  - ▶ Provides compliance assistance and pollution prevention information to the healthcare sector
  - ▶ Funded by EPA's Office of Compliance and managed by EPA's Office of Chemical Safety and Pollution Prevention
  - ▶ [www.hercenter.org](http://www.hercenter.org)
  
- ▶ **"Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States," Revised: August 2008**
  - ▶ A step-by-step guide for developing and implementing a comprehensive pharmaceutical management program in hospitals
  - ▶ Original version (April 2006) was funded by OSWER and managed by Region I; the revision was funded by HERC
  - ▶ <http://www.hercenter.org/hazmat/tenstepblueprint.pdf>

# ORCR Contacts

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## ▶ ORCR Pharmaceuticals Team

### ▶ Lisa Lauer

- ▶ 703-308-7418
- ▶ [lauer.lisa@epa.gov](mailto:lauer.lisa@epa.gov)

### ▶ Jessica Young

- ▶ 703-308-0026
- ▶ [young.jessica@epa.gov](mailto:young.jessica@epa.gov)

### ▶ Kristin Fitzgerald

- ▶ 703-308-8286
- ▶ [fitzgerald.kristin@epa.gov](mailto:fitzgerald.kristin@epa.gov)

## ▶ <http://www.epa.gov/epawaste/hazard/generation/pharmaceuticals.htm>