Pharmaceuticals Rulemaking Update

NEWMOA Webinar

July 25, 2011

Lisa Lauer - ORCR

1

Today We'll Discuss

- Pharmaceuticals rulemaking
  - Background
  - Update
- Reverse Distribution
  - Current interpretations
  - Issues

2

Background: Impetus for Rulemaking

- Original 2008 proposal was a response to numerous inquiries and issues being raised by stakeholders:
  - Hazardous waste regulations not designed for the healthcare setting
    - Healthcare setting is vastly different from the manufacturing setting
  - P-listed wastes and containers
  - Accumulation times
  - Presence of Active Pharmaceutical Ingredients (APIs) in environment

3

Background: Original 2008 Proposal

- Provides a framework for states to add HW pharmaceuticals to their UW programs
- UWR/Pharms proposal published in December 2008
  - ~ 100 comments received
    - States, municipalities, POTW facilities, Federal Agencies, hospitals, RDs, Waste Management/Consulting Services, trade associations and NGOs
  - Majority of commenters generally supported our movement on the issue as a step in right direction, but there were concerns about:
    - Security due to the lack of notification and manifest requirements
    - Lack of education/enforcement
    - Reverse distribution/point of generation
    - Outdated listings

4

Background: 2008 Proposal (cont.)

- Other ORCR priorities prevented progress on the issue during 2010
- In the Fall of 2010, new ORCR Office Director gave the go-ahead and explore other options
  - Explore viable regulatory options, other than UW, to address issues:
    - UW program was deemed too inflexible to address manifest concerns
    - Other pharmaceutical issues would not be addressed with the UW rule
      - Reverse distribution
      - P-listed containers
      - Out-of-date listings

5

What Direction Is EPA Headed?

- Pharmaceuticals Rulemaking
  - Due to concerns over the lack of notification and manifest requirements, ORCR will not finalize the UW/pharmacueticals rulemaking
  - ORCR has initiated the process to investigate other avenues
    - We are hoping to more comprehensively address the issues (e.g., security concerns; management of CS/HW; P-listed containers; reverse distribution)
- Updating HW Listings
  - ORCR is gathering data to ascertain if certain APIs meet the P-listing criteria
  - If ORCR decides to list additional APIs based on the collected data, it will be a separate rulemaking effort

6

Background: Reverse Distribution

- Drug manufacturers provide credit on the return of unused, expired and/or opened/partial pharmaceuticals
- HCFs send the creditable pharms to reverse distributors who calculate the credit on behalf of the manufacturers
- Based on comments from RDs, PhRMA and Walmart to the UWR/Pharms proposal, reverse distribution:
  - Is a marketing incentive
    - HCFs can recover up to the full value of the pharmaceutical from manufacturer if not dispensed
  - Ensures against illicit diversion
    - Manufacturers maintain control of their products up to the point of disposal
    - Controlled substances sent to RDs are tracked and documented IAW the CSA and its implementing regulations
  - Reduces the likelihood of improper disposal
    - RDs oversee the final disposition of drugs (either by incineration or other destruction/disposal method)
    - Without the financial incentive system, HCF could be improperly disposing (i.e., sewering) the creditable drugs
  - Manufacturers use the data collected by reverse distributors on returned drugs to help plan for future production

7

Background: ORCR's Interpretations

ORCR's current interpretations on the RD issue:

- 1981 and 1991 letters from OSW have allowed the return of HW pharmaceuticals to RDs for credit
  - 1991 letter states: "The returned product themselves…are considered more product-like than waste-like (until a determination is made to dispose of them) because recycling by use/reuse is generally a viable option…This view is based on our understanding that the system is established as a means to facilitate the recycling of reusable pharmaceutical products, rather than a waste management system" (RCRA Online# 11606).
- Preamble to the UWR/pharms proposal states:
  - "Because unused or expired pharmaceuticals are being returned (via the reverse distributor) for possible manufacturer credit, they still have potential value to the pharmacy or hospital and are thus not considered wastes" (73 FR 73525; December 2, 2008).

→ **ORCR cannot change current interpretations without providing notice and comment to the public**

8

Background: The Issues

- We now know that the vast majority of drugs sent for credit are not recycled or re-purposed but are discarded
  - Thus the reasoning behind the 1991 letter is moot as recycling and re-purposing is not occurring
  - If it is certain that the drug will be discarded by the RD, is making the decision to send the drug to a RD for credit the same as making the decision to discard that drug?
- There is disagreement over the reasoning that if creditable pharms have value, they are not solid wastes
- The reverse distribution system does not easily fit into the structure of RCRA
- Reverse distribution goes beyond pharmaceuticals
  - A similar system exists for consumer products; however, consumer products can more easily be donated/re-purposed/recycled and do not have the same security concerns

9

Possible Solutions?

1. Adapt the RD system to fit into RCRA
   - POG is at the HCF
   - Require RD to obtain permit for storage of HW
2. Adapt RCRA to fit the RD system
   - Create a new part in RCRA to recognize the uniqueness of the reverse distribution system

- ORCR is planning on investigating the issue

10

Questions? Comments?

Lisa Lauer
ORCR
703-308-7418
Lauer.Lisa@epa.gov

11