Recommended Management Practices for Unused Pharmaceuticals at Health Care Facilities

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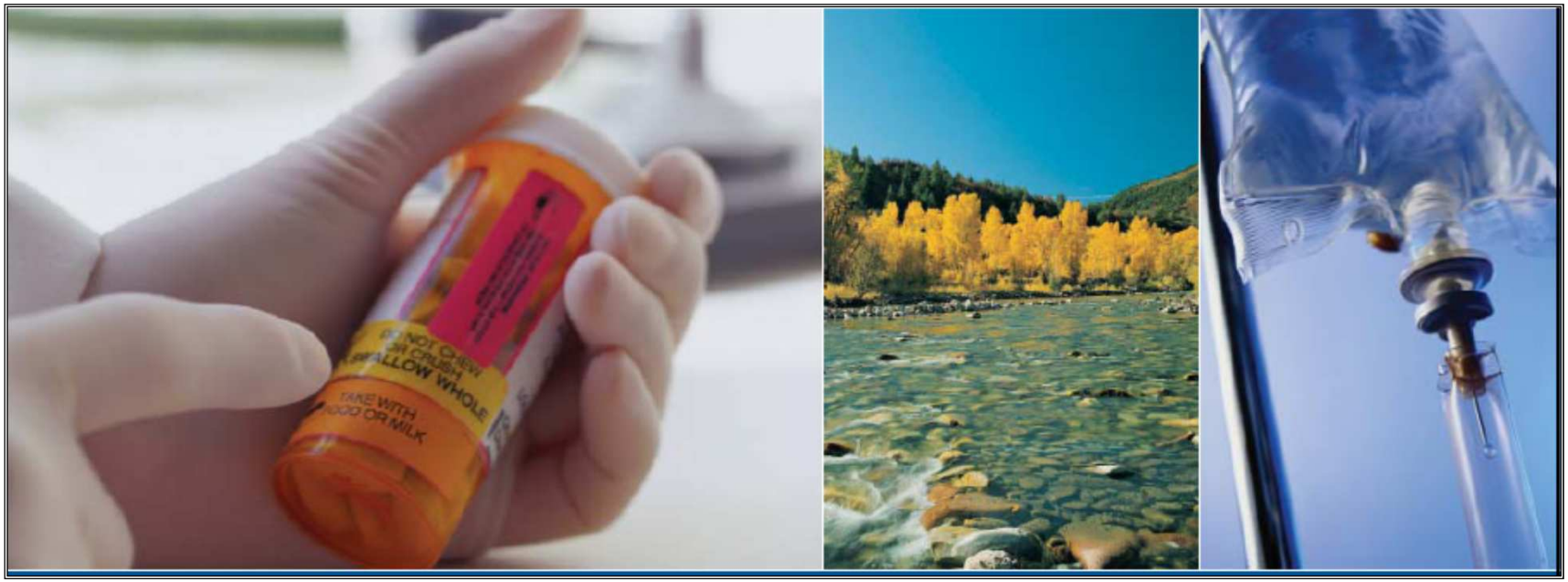

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Overview

- Purpose
- Summary of Draft Guidance Document
- Recommendations from the Draft Guidance Document
- Quick Overview of Public Comments
- Questions/Answers

Purpose

- Pharmaceuticals are being discovered in our nation's waters at very low concentrations.
- While the sources of these pharmaceuticals may be numerous, EPA has been studying unused pharmaceutical disposal practices at health care facilities.
- EPA started a detailed study of the healthcare industry in 2007 to address the concern that potentially large amounts of pharmaceuticals are being flushed or disposed of down the drain, ultimately ending up in rivers.
- EPA is developing guidance to help healthcare facilities manage these unused medicines.

Summary of Draft Guidance Document

- For many years, a standard disposal practice at many health care facilities was to flush unused pharmaceuticals down the toilet or drain. EPA believes that facilities should not dispose of their pharmaceuticals down the drain.
- EPA conducted outreach to a wide range of stakeholders and identified that there is near-universal interest to better manage unused pharmaceuticals at healthcare facilities, as well as general interest in EPA's guidance on managing unused pharmaceuticals.
- The Agency has developed a draft guidance document for health care facilities, which includes, but is not limited to, hospitals, medical clinics, doctors' offices, and long-term care facilities.

Summary of Draft Guidance Document

- In developing the draft guidance document EPA:
  - Contacted over 700 interested stakeholders;
  - Collected data and information from over 30 organizations;
  - Visited fifteen health care facilities and observed their management of unused pharmaceuticals; and
  - Worked with other federal agencies (FDA, CMS, DEA) in the development of the draft guidance.
- EPA announced the availability of the draft guidance document on 8 September 2010.
- EPA received over 90 public comments on the draft and is working on revising the draft guidance document to incorporate these comments. EPA received 35 comments on the preliminary 2010 Plan that supported development of the guidance.
- EPA expects to incorporate these comments into the revised guidance document and publish the final document later this year.

Recommendations from the Draft Guidance Document

- Conduct an inventory of pharmaceuticals being purchased and identify which pharmaceuticals are being disposed.
- Reduce by reviewing purchasing practices, using limited dose or unit dose dispensing, and performing ongoing inventory control and stock rotation.
- Properly manage by identifying types of pharmaceuticals (e.g., controlled substances or hazardous waste) and any federal and state requirements and using EPA recommended practices to dispose of pharmaceutical waste.
- Segregate waste for disposal to ensure compliance with Federal and State laws and train staff.

Draft Guidance Document: Commenters

- Healthcare associations and individual facilities
- Pharmaceutical companies (including PhRMA)
- Federal government (HHS/CMS, VA, US Army, NIH, Naval Med. Center)
- Five states (WA, AR, NY, CO, MN)
- Waste management companies (including reverse distributors)
- Environmental group (Public Employees for Environmental Responsibility)
- Research institutions (UCLA, Univ. of MD)
- Private Citizens (including individual pharmacists)
- POTWs and local government organizations (NACWA, East Bay MUD, Cincinnati, HRSD, San Francisco Municipal Utility District, Minneapolis-St. Paul, Snohomish (WA))

Example Comments: Private Citizens

- Support guidance -- should be made into a regulation. EPA should prohibit flushing of pharmaceuticals by anyone.
- EPA and DEA need to work together to develop practical solutions for disposal of controlled substances.
- Nursing homes should let patients use medications brought from home--which are often 90-day supplies.
- Expand take back programs. There should be a place private citizens can take their unused pharmaceuticals for proper disposal.
- Create a free (government-funded) system to return all unused pharmaceuticals. Remove excessive requirements being placed on narcotic returns.

Example Comments: Waste Management Companies

- Provided very detailed comments including revised table of BMPs by generator size.
- Provides specific comments on inventory management, waste disposal (expand on who can handle waste properly), coordination with DEA, and starting a waste management program.
- Recommends more action from EPA than just simply publishing these BMPs.
- Provided clarifications on defining product vs. waste in reference to reverse distribution.
- Recommend that disposal of unused pharmaceuticals in municipal solid waste should be discouraged as a BMP.

Example Comments: Healthcare Sector

- DEA, FDA and EPA have uncoordinated policies. For example, FDA maintains a list of 30 drugs that are hazardous/controlled and must be flushed (not mixed with undesirable substance).
- Recommends a disposal process that eliminates the need to segregate hazardous and non-hazardous--especially if it's all incinerated. Universal waste rule isn't practical enough relief from RCRA.
- Recommends clarification of terminology, stronger and more specific language related to hazardous waste, and incineration as the preferred disposal method for controlled substances.
- Concerns over DEA acceptance of disposal of unused pharmaceuticals mixed with kitty litter with municipal solid waste.
- Guidance document is too broad and does not meet needs of the long-term care settings. Need to discuss challenges and limitations for each of the recommendations.

Example Comments: Pharmaceutical Sector

- PhRMA commented that ordering smaller container sizes of pharmaceuticals could increase costs of medical care (i.e., medications are cheaper in bulk).
- PhRMA also commented that healthcare facilities have inconsistent approaches to drug storage, which should prohibit the option of re-using some drug returns (even those that are unopened, correctly labeled, and not expired).
- Reductions in purchases may be impractical for some hospitals, use of vouchers conflicts with some state and local regulations, and use of reverse distribution is impractical for smaller facilities.
- One pharmaceutical manufacturer agreed with most of EPA suggestions, such as waste reduction and smaller containers size.

Example Comments: Pretreatment Programs

- Concerned by recommendation to dispose of non-hazardous pharmaceuticals via solid waste landfills. Recommended a change in the guidance to encourage incineration and discourage both sewering and landfilling of pharmaceuticals.

- Recommend firmer language to not perform sewer disposal of unused pharmaceuticals.

- NACWA supported pollution prevention BMPs and reduction of down the drain disposal. BMP should be no drain disposal even for controlled substances (elimination of option not just reduction). Suggest up front summary, table or flow chart of management options.

- Multiple sites under the same company should work together to manage stock; an option for independent facilities is a "buying group" with other facilities.

More Info/Contacts/Questions?

Further updates on the draft guidance document can be found at:

http://water.epa.gov/scitech/wastetech/guide/index.cfm

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