



December 1, 2015

Regina A. McCarthy  
Office of the Administrator  
Environmental Protection Agency  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

Submitted electronically via [www.regulations.gov](http://www.regulations.gov)

**Re: EPA-HQ-RCRA-2007-0932 – Management Standards for Hazardous Waste Pharmaceuticals;  
Proposed Rule**

Dear Ms. McCarthy:

ASHP is pleased to submit comments to the Environmental Protection Agency (EPA) on the agency's proposed rule announced in the Federal Register on September 25, 2015, regarding the draft standards for managing pharmaceuticals determined to be classified as hazardous waste (proposed rule).<sup>1</sup> ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 43,000 members include pharmacists, student pharmacists, and pharmacy technicians. For over 70 years, ASHP has been on the forefront of efforts to improve medication use and enhance patient safety.

ASHP supports actions that reduce or prevent the discharge of pharmaceuticals into the environment. We believe that the presence of all drugs in the environment should be minimized to the extent possible, and we are encouraged by EPA's ongoing effort to create regulatory standards that address this issue.

ASHP has a long history of creating standards for safe handling and disposal of hazardous drugs.. In 1990, ASHP published its revised *Technical Assistance Bulletin on Handling Hazardous Drugs*.<sup>2</sup> This guidance was used by the NIOSH Working Group on Hazardous Drugs as a framework for recommendations published in the *NIOSH Alert: Preventing Exposure to Antineoplastics and Other Hazardous Drugs in Health Care Settings*.<sup>3</sup> Our current *ASHP Guidelines on Handling Hazardous Drugs* includes a description of the Resource Conservation and Recovery Act (RCRA) rules related to

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<sup>1</sup> Federal Register, Volume 80, No. 186. Pages 58,014–58,092

<sup>2</sup> American Society of Hospital Pharmacists. ASHP technical assistance bulletin on handling cytotoxic and hazardous drugs. *Am J Hosp Pharm*. 1990; 47:1033-49

<sup>3</sup> National Institute for Occupational Safety and Health. NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings. <http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf> (accessed 19 Nov 2015).

pharmaceuticals.<sup>4</sup> Pharmacists handle hazardous drugs on a daily basis; therefore, using best management practices for disposal is an important issue for them. ASHP commends the EPA for recognizing that the fundamental differences between industrial and/or chemical waste and pharmaceutical waste require a new and distinct group of regulations. Additionally, we appreciate the efforts of the EPA to streamline and simplify the disposal process. Pharmacists have sometimes struggled with interpreting RCRA regulations for handling of industrial chemicals in a manner that would appropriately apply to drugs, despite ASHP's efforts to provide resources and tools to help them comply. We continue to receive requests for assistance in navigating and complying with the layers of existing federal, state, and local disposal regulations. ASHP views the proposed new rule as a key opportunity to resolve questions and concerns, and we look forward to working with the agency as they refine these regulations.

We also commend the EPA for working collaboratively with the Drug Enforcement Administration (DEA), Nuclear Regulatory Commission (NRC), Department of Transportation (DOT), and other federal agencies in a proactive manner to prevent inconsistencies and overlaps between the new rule and existing regulations.

#### **General comments**

The new rule simplifies steps in the waste process for healthcare facilities by exempting certain materials, such as empty vials or containers and sharps from RCRA regulation. Pharmaceuticals as a class are exempted from such requirements as biennial reporting, limiting periods of collection, weighing hazardous waste pharmaceuticals (HWPs) for generator classification, and logging manifests and using special carriers when shipping to reverse distributors. While ASHP anticipates that these changes will be positive, questions may arise during the transition period to the new procedures and definitions. We encourage the EPA to provide practical tools and resources for implementation or official guidance, similar to the 2010 *Best Management Practices for Unused Pharmaceuticals at Health Care Facilities*.<sup>5</sup> We also encourage the EPA to work with the writers of *Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States* to update this guidance after a final rule has been issued.<sup>6</sup>

It is unfortunate that the EPA does not provide a reliable instrument that healthcare providers can use to make a hazardous waste determination. EPA has acknowledged the numerous challenges it experienced when attempting to apply 40 CFR 261 Subpart C to pharmaceuticals in its *Data Collection on the Toxicity, Use, and Disposal of Hazardous Drugs Report* (September 2011). These include lack of needed information on toxicity and other properties as well as inability to gauge the potential threat to public health or the environment by mishandling pharmaceutical waste, as unlike industrial waste, the amount that enters the environment can only be estimated.

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<sup>4</sup> ASHP. ASHP Guidelines on Handling Hazardous Drugs.  
<http://www.ashp.org/DocLibrary/BestPractices/PrepGdlHazDrugs.aspx> (accessed 19 Nov 2015)

<sup>5</sup> Environmental Protection Agency. Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities.  
<http://water.epa.gov/scitech/wastetech/guide/upload/unuseddraft.pdf> (Accessed 19 Nov 2015)

<sup>6</sup> Practice Greenhealth. Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States. <http://www.hercenter.org/hazmat/tenstepblueprint.pdf> (Accessed 19 Nov 2015).

These factors are additionally confounding for healthcare providers attempting hazard determination, as according to the EPA's own assessment, providers lack the necessary expertise to accurately assess the thousands of pharmaceutical substances that may be used in their organizations. Lists of pharmaceuticals that may fall under RCRA regulations are inconsistent, ranging from 28 identified drugs<sup>7</sup> to 92<sup>8</sup>, all with disclaimers that they are not all-inclusive. In light of the significant fines imposed for mishandling of hazardous waste, hospitals often turn to third-party contractors for services such as hazard determination, setup of procedures for appropriate waste stream disposition, and staff training.

In Section VII of the proposed rule's preamble, EPA asks, "should EPA develop and promulgate new criteria specific to discarded pharmaceuticals" that would allow it to list drugs separately. ASHP believes that this would be a more effective method of communicating EPA's expectations and controlling environmental contamination with pharmaceuticals. We echo the comments of others that RCRA (and other acts for controlling pollutants) were not developed to address pharmaceutical waste. Continued attempts to retrofit or interpret them to apply to pharmaceutical waste may perpetuate confusion and not achieve EPA's goals. Additional recommendations are offered in the next section.

### **Responses to EPA's request for specific comments**

#### *Definitions*

*"Pharmaceutical" — any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act (FD&C Act), prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from the spills of pharmaceuticals.*

ASHP is unable to determine the benefit to healthcare facilities or public health that may occur by managing dietary supplements under the proposed new rule. Such an action would require additional hazard determinations by generators for an extremely large class of non-standardized and chemically diverse substances. While ASHP is aware of certain supplement components, such as germanium, aconite, or yohimbine, which may be hazardous or toxic, we could not find the information required for a hazard determination. Other contaminants of dietary supplements, such as mercury and arsenic, are not detectable except by analysis following adverse event reports. We recommend that the rule include only dietary substances regulated as drugs at this time, and that EPA further consult with the FDA to determine which EPA-listed substances are present in dietary supplements and, if so, whether supplements are labeled as such.

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<sup>7</sup> Massoomi, F. et.al. Implementing a safety program for handling hazardous drugs in a community hospital. *Am J Health-Syst Pharm*—Vol 65 May 1, 2008

<sup>8</sup> List of pharmaceuticals that are potentially hazardous wastes when discarded. Florida Department of Environmental Protection. [http://www.dep.state.fl.us/waste/pharm/documents/Waste-Pharm-List\\_Dec07.pdf](http://www.dep.state.fl.us/waste/pharm/documents/Waste-Pharm-List_Dec07.pdf). Accessed November 20, 2015.

We advise the EPA that compounding pharmacies are using bulk substances for compounding that may be hazardous, and we do not know how disposal of these products is regulated. Although the proposed definition for pharmaceutical includes “prescription drugs” in the rule, which would encompass compounded drugs, we recommend for clarity that EPA specifically include “compounded drugs” in its language.

“Hazardous waste pharmaceuticals” — The various terms proposed for HWPs are based on their status or eligibility for receiving credit.

ASHP recommends simpler terms for EPA’s consideration, as follows:

- Potentially creditable HWP – *HWP returned for credit*. HWPs that the healthcare organization submits for evaluation of eligibility for manufacturer’s credit
- Non-creditable HWP – *HWP returned for disposal*. HWP for which credit is not requested or that is deemed not eligible for credit by the healthcare organization
- Evaluated HWP – *RD-HWP for disposal*. HWP evaluated by a reverse distributor as not eligible for credit and designated for disposal

#### *Identifying additional pharmaceuticals as hazardous wastes*

The EPA, citing a 2012 Office of the Inspector General (OIG) report, requests comments on two of its recommendations — identifying additional HWPs and expanding pharmaceuticals designated as hazardous waste.<sup>9</sup>

ASHP agrees with the recommendation in the OIG report to update and maintain the current EPA lists of chemicals and other substances, and we understand EPA’s rationale for not addressing this issue. Nevertheless, we are concerned that EPA listing criteria do not address a pharmaceutical characteristic that may present a risk to public health. In the final *Data Collection on the Toxicity, Use, and Disposal of Hazardous Drugs Report*, the authors contracted by EPA note that only 11 drugs from the combined NIOSH and OSHA lists meet EPA’s toxicity criteria for listing, three of which are already listed. However, we note that five IARC Class 1 carcinogens are not mentioned because they also do not meet EPA’s criteria.<sup>10</sup> The EPA notes in its preamble to the proposed rule that it supports the 10-Step Blueprint recommendation for hazardous incineration of pharmaceuticals that have “hazardous waste-like” properties, but are not regulated by RCRA Subtitle C.

ASHP recommends two possible actions that EPA might take for expanding the list of pharmaceuticals considered hazardous waste to include human carcinogens:

1. **EPA-authored compliance guidance that identifies pharmaceuticals for which the rule is not applicable but for which disposal as HWPs is recommended.** A specific list for healthcare

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<sup>9</sup> U.S. Environmental Protection Agency, Office of the Inspector General. EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal. <http://www2.epa.gov/sites/production/files/2015-09/documents/20120525-12-p-0508.pdf> (Accessed 19 NOV 2015).

<sup>10</sup> These compounds are busulfan, etoposide, azathioprine, cyclosporine, and estrogen/progesterone combinations.

communities would remove any ambiguity for the regulated entities and result in better disposal practices. We do not believe rule-making to be necessary. Similar lists are provided by NIOSH in its updates and are essential references for both healthcare providers and regulatory groups, OR

2. **Include carcinogenicity in the criteria for listing a substance as hazardous.** Alternatively, EPA could initiate rule-making that includes pharmaceutical carcinogens as a listing criterion. ASHP recommends that EPA also consider whether other properties of drugs that are NIOSH- or OSHA-listed merit a new healthcare sector-specific list of hazardous waste pharmaceuticals that require disposal under Subpart P.

#### *Non-HWPs with no hazardous-like properties*

ASHP supports EPA's endorsement of the methods recommended in the 10-Step Blue Print to dispose of nonhazardous pharmaceuticals either by regulated medical waste incineration or waste-to-energy municipal incineration. However, while we have recommended that additional pharmaceuticals should be included under the rule, we believe that disposing of all pharmaceuticals as hazardous waste may not be financially feasible for many healthcare organizations.<sup>11</sup>

#### *Personnel training requirements in rule*

Pharmacy staff is already trained to handle hazardous chemotherapy drugs, including spill management and disposal. The type of training EPA proposes in the new rule could likely be integrated into this program. Due to the importance of placing the correct substances into the appropriate waste stream, ASHP recommends not relying on training alone, but using visual cues, such as color-coded containers; reminders, such as precautionary statements in electronic records; and labels on the immediate outer packaging of the medications to supplement learning, if feasible. Rather than annual retraining, we recommend annual competency assessment and retraining if knowledge or skills do not meet requirements. With regard to documentation, standards-setting and accreditation groups already require this.

#### *Reporting requirements for healthcare facilities*

We agree with EPA's proposal to exempt pharmaceutical waste from inclusion in the biennial report healthcare facilities are required to submit for other hazardous waste, as these materials are not relevant to a facility's generator status. In response to EPA's request for comments on additional reporting of quantities and disposition of non-creditable hazardous waste that may be required, we request more detail on the intent of this requirement.

#### *Ban on sewerage*

ASHP supports EPA's proposed ban on sewerage of HWPs, as well as non-hazardous pharmaceuticals, except for those that do not contain active pharmaceutical ingredients, such as sterile water and 0.9% sodium chloride for injection and irrigation.

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<sup>11</sup> According to a 2008 article in the American Journal of Health-System Pharmacy, each RCRA-approved 8-gallon container costs \$12.41 and RCRA-regulated waste removal costs \$42.03 per pound. Am J Health-Syst Pharm—Vol 65 May 1, 2008

Environmental Protection Agency  
December 1, 2015  
Page 6

ASHP appreciates the opportunity to comment on the EPA's proposed rule on the management standards for HWPs. Please contact me if you have any questions or wish to discuss our comments further. I can be reached by telephone at 301-664-8806 or by e-mail at [ctopoleski@ashp.org](mailto:ctopoleski@ashp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Christopher J. Topoleski". The signature is fluid and cursive, with a large initial "C" and "T".

Christopher J. Topoleski  
Director, Federal Legislative Affairs