



March 4, 2009

RCRA Docket
Environmental Protection Agency
Mailcode: 2822T
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Re: Docket ID No. EPA-HQ-RCRA-2007-0932, Amendment to the Universal Waste Rule: Addition of Pharmaceuticals

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit comments pertaining to the Amendment to the Universal Waste Rule: Addition of Pharmaceuticals Proposed Rule. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

ASHP has long supported the safe handling of hazardous drugs that may present an acute or chronic hazard to patients and health care practitioners. This concern extends to the impact of pharmaceutical waste products on the environment. The Society publishes the ASHP Guidelines on Handling Hazardous Drugs, which recommends safe practices for the preparation, administration and disposal of hazardous pharmaceutical products. Pharmacists are the medication experts and, together with pharmacy technicians, these individuals play a leading role in managing the proper disposal of pharmaceutical wastes, including hazardous drugs and controlled substances.

ASHP's policy is:

1. To work closely with regulatory bodies and appropriate organizations to develop standards that address pharmaceutical hazardous waste as defined in the Resource Conservation and Recovery Act (RCRA), for the purpose of simplifying the disposal of these substances in health systems;

2. To encourage pharmaceutical manufacturers and the Environmental Protection Agency (EPA) to provide guidance and assistance to health systems in their pharmaceutical waste-destruction and waste-recycling efforts;
3. To promote awareness of pharmaceutical waste regulations within health systems;
4. To encourage pharmaceutical manufacturers to streamline packaging of drug products to reduce waste materials.

Documentation and tracking

ASHP commends EPA for developing this proposed rule that would add hazardous pharmaceutical wastes to the Universal Waste Rule (UWR). The proposed rule would reduce the complexity of the RCRA hazardous waste generator regulations for pharmaceutical wastes, and streamline the collection and handling requirements. However, ASHP does not support the addition of pharmaceutical wastes to the UWR unless the EPA requires proper documentation and tracking of pharmaceutical wastes after they leave the health care facility. While pharmaceutical wastes meet many of the characteristics of UWR products (for example, small quantities and large numbers of generators), safety and product integrity concerns make these products unique.

EPA should require that regulated and/or registered, specialized removal companies engage in the removal of drug products under the UWR, and document the products from their removal from the health care facility to their ultimate disposition/destruction. This documentation could be accomplished through the use of the current Uniform Hazardous Waste Manifest, or a similar process. Product integrity and patient safety would be adversely affected if these safeguards are not implemented. It is important to note that the inclusion of pharmaceutical wastes in the UWR does not preclude health care facilities from being fined for RCRA violations. Therefore, it is critical that facilities be assured of the final destruction of their wastes by requiring documentation on the part of the waste removal companies.

Unused pharmaceuticals and empty packaging are significant concerns. Unused product which has not been maintained under proper storage conditions (e.g., light, temperature) may unintentionally or intentionally re-enter the supply chain. Empty packaging, including vials, are high-demand items that support counterfeit drug operations. EPA should include provisions in its final rule to ensure that unused product and empty packaging do not re-enter the supply chain, so patients will not be in danger of receiving improperly labeled and packaged, deteriorated, outdated, counterfeit, or unapproved drug products.

ASHP supports the development of health-system policies that are designed to deter drug product theft and thereby enhance both the integrity of the drug distribution chain and the safety of the workplace. The Society further encourages the development of systems that

limit the diversion and abuse potential of medications, including high-cost drugs and controlled substances, thereby reducing the likelihood that these products will be stolen.

Need to update P- and U-lists

ASHP encourages EPA to re-examine and update its P- and U-lists of hazardous wastes to address the development and availability of highly toxic pharmaceuticals since the 1970s, including certain chemotherapy drugs. These updates are necessary to provide better direction to affected entities as improvements to pharmaceutical waste management are implemented, and health care facilities develop and maintain their own lists of hazardous wastes.

ASHP believes that, while training and storage requirements under UWR are decreased, they will still be burdensome for smaller facilities, especially those without dedicated staff. Larger facilities already have systems in place to manage compliance issues related to the disposal of hazardous pharmaceutical wastes. These facilities would be able to minimize costs under the UWR by allowing for greater accumulation of wastes and less frequent use of outside services to remove them. At a small facility, the pharmacy director or assistant director would likely manage the disposal process along with all the other day-to-day operational issues, which may be burdensome to the facility. ASHP is pleased that the UWR will be optional for facilities in states that are not RCRA-authorized, and in RCRA-authorized states that choose to adopt the final regulation.

Need for training

While the proposed rule would alleviate certain regulatory concerns, ASHP believes proper staff training will still be a significant issue. EPA notes that, while the UWR regulates only RCRA hazardous wastes, the Agency anticipates that including pharmaceutical wastes in the UWR will encourage persons to manage other pharmaceutical wastes in the same manner, particularly those wastes that are not hazardous under RCRA, but which may nonetheless pose risks. ASHP disagrees with this assumption. Facilities likely would not dispose of non-RCRA drugs under the UWR since the high cost of specialized removal companies would be a deterrent.

EPA should be aware that, without proper staff training, costs for pharmaceutical waste disposal may increase in some facilities, since they may take a more cautionary approach and dispose of items unnecessarily through the UWR. The need for education, particularly in nursing and other departments external to pharmacy, will be extensive. ASHP strongly recommends that EPA play a major role in facilitating this education.

Use of reverse distributors and manufacturers

ASHP strongly recommends that EPA not allow manufacturers of pharmaceuticals and pharmaceutical reverse distributors to manage waste pharmaceuticals under the UWR. Manufacturers have the expertise available to determine whether their wastes are

hazardous. In addition to process waste, which could include bulk chemicals, manufacturers may generate and dispose of large quantities of off-specification products. Wastes generated by manufacturing facilities do not meet the eight criteria of universal waste, and should be managed under RCRA. Similarly, reverse distributors generate large volumes of wastes, and should continue to be managed as generators under RCRA.

Container requirements

The proposed container requirements for pharmaceutical universal wastes do not include the requirement that containers be “closed.” EPA believes that most pharmaceutical universal wastes would be unused in their original packaging when disposed of, and so accumulating these wastes in a larger container would pose little, if any, risk of release through spillage, leakage, or emission to the air. This assumption by EPA is incorrect. Drug wastes can be in the form of single tablets, compounded intravenous solutions, partial vials, etc. Therefore, ASHP strongly recommends that collection containers should be closed or covered at all times, except when waste is being added to or removed from the containers, in order to prevent exposure to health care facility employees and also prevent diversion.

Patient confidentiality

Many pharmaceutical wastes, including IVs, contain labeling with patient information that should be de-identified, particularly if removal and ultimate disposal is undocumented, since under those circumstances, facilities would be unable to guarantee that wastes would be handled in a way that maintains patient confidentiality.

Risk of drug exposure

ASHP has concerns about the risk of drug and human infectious wastes exposure by staff working at removal companies. ASHP encourages EPA to utilize our Guidelines on Handling Hazardous Drugs:

<http://www.ashp.org/DocLibrary/BestPractices/ASHPGuidelinesHandlingHazardousDrugs.aspx>. These Guidelines provide an update on new and continuing concerns for health care workers’ handling of hazardous drugs, and provide recommendations.

Cost reductions

With the implementation of the UWR, EPA estimates a cost reduction of \$33.9 million to \$35.2 million per year for hospitals and reverse distributors combined. While ASHP agrees that it is likely that individual facilities will see reduced costs for disposal, it is difficult to determine the true impact. ASHP recommends that EPA obtain accurate estimates of the amounts disposed, especially for drugs that extend beyond RCRA. To obtain these estimates, EPA could perform pilot studies in a variety of practice settings (e.g. small, rural, community, and large academic settings). EPA could make the results

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of the studies publicly available, to help facilities determine whether implementing the UWR would be beneficial to them.

Identification of hazardous wastes

EPA should recognize that manufacturers must play a role in identifying which drugs are hazardous, particularly for those drugs that are not specifically U- or P-listed, but have characteristics such as ignitability, corrosivity, reactivity, or toxicity. ASHP encourages EPA to work with FDA to reduce the burden on health care providers, and address this issue in standardized product labeling.

ASHP appreciates this opportunity to present its comments pertaining to the proposed rule. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

A handwritten signature in cursive script that reads "Justine Coffey".

Justine Coffey, JD, LLM

Director, Federal Regulatory Affairs