

Preparation and Handling

Pharmaceutical Waste (0903)

Source: Council on Pharmacy Practice

To collaborate with regulatory bodies and appropriate organizations to develop standards for the disposal of pharmaceutical hazardous waste as defined in the Resource Conservation and Recovery Act (RCRA), for the purpose of simplifying the disposal of these substances by health systems; further,

To encourage pharmaceutical manufacturers and the Environmental Protection Agency (EPA) to provide guidance and assistance to hospitals and health systems in proper pharmaceutical waste disposal and destruction efforts; further,

To advocate that EPA update the list of hazardous substances under RCRA and establish a process for maintaining a current list; further,

To urge federal, state, and local governments to harmonize regulations regarding disposal of hazardous pharmaceutical waste; further,

To advocate that the Food and Drug Administration standardize labeling of drug products with information relating to appropriate disposal; further,

To promote awareness within hospitals and health systems of pharmaceutical waste regulations; further,

To encourage research on the environmental and public health impacts of drug products and metabolites excreted in human waste; further,

To encourage pharmaceutical manufacturers to streamline packaging of drug products to reduce waste materials.

This policy was reviewed in 2013 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Safe Disposal of Patients' Home Medications (0614)

Source: Council on Professional Affairs

To minimize the patient safety consequences and public health impact of inappropriate disposal of patients' home medications by working collaboratively with other interested organizations to (1) develop models for patient-oriented medication disposal programs that will minimize accidental poisoning, drug diversion, and potential environmental impact, (2) advocate that the pharmaceutical industry and regulatory bodies support the development and implementation of such models, and (3) educate health professionals, regulatory bodies, and the public regarding safe disposal of unused home medications.

This policy was reviewed in 2015 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Safe and Effective Extemporaneous Compounding (0616)

Source: Council on Professional Affairs

To affirm that extemporaneous compounding of medications, when done to meet immediate or anticipatory patient needs, is part of the practice of pharmacy and is not manufacturing; further,

To support the principle that medications should not be extemporaneously compounded when they are commercially and readily available in the form necessary to meet patient needs; further,

To encourage pharmacists who compound medications to use only drug substances that have been manufactured in Food and Drug Administration-approved facilities and that meet official United States Pharmacopeia (USP) compendial requirements where those exist; further,

To support the principle that pharmacists be adequately trained and have sufficient facilities and equipment that meet technical and professional standards to ensure the quality of compounded medications; further,

To encourage USP to develop drug monographs for commonly compounded preparations; further,

To educate prescribers and other health care professionals about the potential risks associated with the use of extemporaneously compounded preparations.

This policy was reviewed in 2015 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate..

ASHP Policy Positions 2009–2016 (with Rationales)

Drug Distribution and Control: Preparation and Handling

0903

PHARMACEUTICAL WASTE

Source: Council on Pharmacy Practice

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To encourage pharmaceutical manufacturers and the Environmental Protection Agency (EPA) to provide guidance and assistance to hospitals and health systems in proper pharmaceutical waste disposal and destruction efforts; further,

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To advocate that the Food and Drug Administration standardize labeling of drug products with information relating to appropriate disposal; further,

To promote awareness within hospitals and health systems of pharmaceutical waste regulations; further,

To encourage research on the environmental and public health impacts of drug products and metabolites excreted in human waste; further,

To encourage pharmaceutical manufacturers to streamline packaging of drug products to reduce waste materials.

This policy supersedes ASHP policy 0231.

Rationale

ASHP seeks to define pharmacists' responsibility to the public for safe disposal of hazardous pharmaceutical waste as well as to assist with their responsibility to comply with applicable regulations. ASHP believes that barriers to safe disposal of hazardous pharmaceutical waste include obsolete waste lists, variability in requirements, inadequate labeling, and a lack of research.

Obsolete lists. The waste stream for hazardous pharmaceuticals is in part determined by the RCRA waste list (i.e., P or U list) to which the drug is assigned. However, these lists do

not include all medications, especially newer products. If a drug is not listed, individual organizations either follow the method of disposal listed for similar drugs or drug classes or use no special disposal method at all. Minimally hazardous drugs are included on these lists, creating needlessly burdensome disposal requirements.

Variability in requirements. Regulations vary from state to state and even from county to county. Large hospital systems are forced to create site-specific policies, which complicates communication and education about the appropriate management of waste.

Labeling. Ensuring that products for disposal are directed into the proper waste stream is left up to health care organizations. Many apply auxiliary labeling on-site to communicate this information. It would be more logical and efficient for the manufacturer to include this information in product labeling. Labeling immediate containers with disposal directions would ensure that this information reached the end-user of the product. One example of how this might be done is the method used by the National Fire Protection Agency, which identifies hazards with specific symbols.

Research. Little research or guidance is available on the environmental effect of hazardous metabolites excreted in human waste. More research is needed in this area.