Hazardous Waste Compliance In Health Care Settings

Rita M. Marcoux, RPh, MBA; and F. Randy Vogenberg, RPh, PhD

Keywords: pharmaceutical waste, medication, drug and waste or wastage, pharmaceutical and personal care products, Resource Conservation and Recovery Act, Environmental Protection Agency, Drug Enforcement Administration

Abbreviations: Drug Enforcement Administration (DEA), Environmental Protection Agency (EPA), National Institute for Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), pharmaceutical and personal care products (PPCP), Resource Conservation and Recovery Act (RCRA), United States (U.S.), U.S. Geological Survey (USGS)

INTRODUCTION

Prescription medications are an important part of maintaining health and improving quality of life for millions of Americans. However, not all medications dispensed to patients are consumed. Appropriately prescribed medications may go unused for a variety of reasons, including: the patient’s medical condition has been resolved before the medication is completely consumed; the patient’s medication supply is not used completely prior to its expiration date; the medication causes an adverse effect and the patient must stop therapy; the medication is ineffective and the physician switches the patient to a different medication; the patient fails to adhere to the prescribed therapy; or the patient dies and leaves behind a supply of medication.1

The topic of pharmaceutical waste has gained recognition in recent years as an increasingly urgent public health and environmental protection issue. The Drug Enforcement Administration (DEA), Environmental Protection Agency (EPA), Centers for Medicare and Medicaid Services (CMS), and Food and Drug Administration (FDA) have all taken steps to address the problem of pharmaceutical waste in both the community and institutional settings. However, these efforts have not been coordinated and have sometimes conflicted with one another.2 This article provides an update on key legislation and regulations that have emerged as important issues for health care entities to address.3

RESEARCH LEADS TO CHANGES

The generation of prescription drug waste in hospitals, long-term-care facilities (LTCFs), and retail pharmacy practice has a long history of discussion and research. LTCFs offer an example that led to state, regional, and national changes.

Medication waste in LTCFs can include any medication that has been dispensed and paid for, but not consumed, by a particular patient.4 In 1987, Kidder reviewed 13 studies that addressed the magnitude of drug waste in LTCFs.5 In 1992, Shina­viera and Kirk assessed medication waste in selected central Texas LTCFs under the same corporate ownership; of 999 prescriptions analyzed, a quantity of 77 (7.7%) was wasted, accounting for $780 (3.7%) of the total prescription ingredient cost of $20,889.6

Paone et al. conducted a two-year (1992–1994) prospective study that evaluated the scope and costs of medication waste in Massachusetts LTCFs.7 They determined the quantity of medications wasted, expense of medications wasted, and reasons for medication waste for 2,360 residents of 17 LTCFs using a data-collection form that was completed by nurses at each facility and collected by consultant pharmacists at monthly intervals. Collectively, 198 months of data representing 852,300 patient days were obtained. Using ingredient costs, the expense of medication waste was estimated at $0.15 per patient day ($4.50 per patient per month); allowing for an average of 8% inflation in medication expenses, the average cost of medication waste based on Kidder’s review would be $6.74 (in 1993 dollars). Wasted medication at the 17 LTCFs in Paone et al. accounted for an estimated 6.7% of the cost of the medications dispensed (range, 1.77% to 11.39%). More than 90% of medication waste resulted from patient deaths; discontinued medications; medication changes; and patient hospitalizations, transfers, or discharges.

Cumulative LTCF research resulted in administrative and/or regulatory actions by CMS, the American Medical Association, the American Medical Directors Association, and the American Society of Consultant Pharmacists in addition to state and federal drug-control agencies. Such actions included improved drug-disposal options, return-for-reuse policies, credits for returns, and other drug-management options and inter-agency coordination that had previously been prohibited or discouraged by law or regulation.

FEDERAL LAW AND REGULATION

In October 1976, amid growing concern over the volume and impact of waste being generated in the United States, Congress passed the Resource Conservation and Recovery Act (RCRA), which applied to solid waste and hazardous waste.

The first RCRA regulation, Hazardous Waste and Consolidated Permit, published in the Federal Register in May 1980, defined a “cradle to grave” approach to handling hazardous waste.8 Congress amended and strengthened the RCRA with the Hazardous and Solid Waste
Amendments of 1984, the Federal Facility Compliance Act of 1992, and the Land Disposal Program Flexibility Act of 1996. Each of these acts further defined the scope of the RCRA and strengthened the EPA’s enforcement penalties.

The EPA soon began to investigate pharmaceutical waste accumulation in U.S. water sources and its impact. In 1999, the agency published its findings in Environmental Health Perspectives and coined the term pharmaceutical and personal care products (PPCP), which “refers, in general, to any product used by individuals for personal health or cosmetic reasons or used by agribusiness to enhance growth or health of livestock. PPCPs comprise a diverse collection of thousands of chemical substances, including prescription and over-the-counter therapeutic drugs, veterinary drugs, fragrances, lotions, and cosmetics.”

Other groups have also contributed investigative efforts. Survey results from 1999 and 2000 under the Toxic Substances Hydrology Program of the U.S. Geological Survey (USGS) found that 80% of U.S. streams contained one or more pharmaceuticals. And since the early 2000s, the U.S. Fish and Wildlife Service and the USGS have been evaluating environmental activities that are potentially responsible for a type of intersex fish: males with oocytes in their testes and/or vitellogenin in their blood. In 2009, the USGS reported widespread findings of intersex fish (mostly smallmouth and largemouth bass) throughout the United States. Although no specific chemical or environmental stressor has been identified as the causative factor, the impact of endocrine-disrupting chemicals tops the list of suspects.

With an estimate of more than 70,000 chemicals used regularly worldwide, the EPA is working with the U.S. Labor Department’s Occupational Safety and Health Administration (OSHA), the DEA, and the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control and Prevention, as well as private organizations such as The Joint Commission, to identify, address, and enforce safe handling procedures for wastes. However, interpreting and complying with federal regulations can be complicated by individual states’ regulations. This growing body of regulation is having a significant operational and fiscal impact on health care providers’ handling of pharmaceutical waste in their facilities.

**RESOURCE CONSERVATION AND RECOVERY ACT**

Health care organizations are being influenced in multiple ways to improve their waste programs. The Joint Commission has specifically included hazardous waste management in two of its standards, Medication Management and Environment of Care. Medical waste vendors have become increasingly vigilant about refusing to accept mixed streams of waste: Hazardous waste cannot be discarded with medical waste in red bags.

Under the RCRA, a solid waste is hazardous waste if it exhibits one of four characteristics—ignitability, corrosivity, toxicity, or reactivity—or if it is specifically named on one of the four EPA lists of hazardous waste, F, U, P, and K, in 40 CFR §261.2, subpart D. Drugs listed under P and U include specific unused chemicals; drugs under U are toxic, while those under P are considered acutely toxic. The most common U-list drugs are chemotherapeutic agents (Table 1). A container with less than 3% of its volume remaining is considered “RCRA empty” and can be discarded as medical waste. Containers that are not “RCRA empty” are considered bulk waste and must be discarded as hazardous waste. The RCRA website includes an online database of the EPA's published materials that can be accessed for guidance in managing waste. However, there is no comprehensive list of chemicals that health care entities may use as a reference for compliance. Existing lists are updated continuously as state and federal agencies determine whether a chemical is hazardous waste based on the RCRA and/or on state regulations, which may be more stringent. In 2008, the EPA proposed an amendment to the RCRA that would address pharmaceutical waste. The comment period ended in 2009, but the EPA never published final regulations.

In 2012, a report by the EPA Office of Inspector General identified more than 100 drugs that met the RCRA definition for hazardous waste but may not have been reviewed by the EPA. The report highlighted an OSHA list that identified 61 pharmaceuticals as hazardous waste and a 2010 NIOSH list of 157 drugs (Table 1). Accurate identification of hazardous waste is essential for a health care facility. Facilities that generate more than 220 pounds of hazardous waste or more than 2.2 pounds of P-listed waste a month are considered large-quantity generators. Large-quantity generators must receive an EPA identification number and notify the EPA of their waste-generation activities. Many states include the NIOSH and RCRA lists of drugs in their hazardous waste management requirements. Non-RCRA pharmaceutical waste and items not included on any current lists continue to raise environmental concerns and are managed by some states through their own regulations. In early 2014, the EPA announced that it was developing a new proposal to establish standards for the management and disposal of pharmaceutical waste.

The management of controlled substances as waste falls under the DEA’s jurisdiction. The volume of controlled substance waste collected during national “take-back” campaigns (meant to prevent the diversion of controlled substances) helped prompt the DEA to issue a final rule in accordance with the Secure and Responsible Drug Disposal Act of 2010. DEA’s Disposal of Controlled Substances final rule allows certain DEA registrants to modify their registrations to become authorized collectors. Collectors are responsible for ensuring that collected controlled substances are rendered “nonretrievable” and that destruction is recorded as required by 21 CFR, part 1304. A letter from the DEA on October 17, 2014, reminded practitioners that drugs administered to patients remain under the control of the practitioner until those drugs are fully exhausted. Any remaining or unused drug must be recorded, stored, and destroyed in accordance with 21 CFR §1304.22(c) and should never be discarded in an institutional collection receptacle.

**COMPLIANCE AND PENALTIES**

Health care organizations often seek help from vendors to manage this complex, fluid administrative burden. Vendors such as Stericycle, Waste Management, and Clean Harbor offer an array of services, including online databases, onsite reviews and audits, and blogs to assist their clients in managing their waste streams at economical rates.
The cost of removal depends on the type of waste. It is incumbent on facilities to ensure that their policies and procedures facilitate the correct separation of waste. For example, products such as Rx Destroyer and Cactus Smart Sink are available to help manage controlled substances and nonhazardous waste for health care facilities. These products render the medication nonrecoverable and nonretrievable to meet DEA standards. In some states, the end product of these systems may be discarded as solid waste.

The quagmire of state and federal regulations is difficult for health care professionals to navigate, but the consequences for noncompliance can be severe. Congress empowered the EPA to level significant fines against corporations and those responsible for compliance. Section 3008(a) of the RCRA gives the EPA authority to levy administrative, civil, or criminal penalties. Fines may reach up to $37,500 a day per occurrence. Six of the seven potential criminal offenses carry penalties of up to $50,000 a day per occurrence and up to five years in jail. The EPA has 10 regional offices responsible for oversight in specific states, tribal areas, and territories. To help users obtain state-specific information, the EPA website offers a table of state-specific links for hazardous waste regulations. State regulations may permit additional significant fines. The EPA’s Enforcement and Compliance History Online dashboard allows users to analyze state activities and enforcement pertaining to hazardous waste. A review of the dashboard shows California and Missouri, for instance, are actively enforcing their regulations. In 2013, Walmart pleaded guilty to hazardous waste violations in both of those states and with the EPA. The fines totaled $82 million, with the EPA receiving $7.6 million, California $60 million, and Missouri $14 million.

### CONCLUSION

LTCFs illustrate how broad practice changes were driven by health care professionals in response to waste issues and interagency contradictions that affected patient care. A similar effort by hospitals, combined with quality-of-care initiatives by The Joint Commission and other accreditation organizations, has also influenced these institutions’ drug waste and disposal practices.

In recent years, the initiative has shifted to the rule of law in addressing waste problems, led by the EPA under legislation passed by Congress. Health care organizations face increased financial risks as a result of steep penalties and other potential sanctions if they do not effectively manage drug waste to protect the environment. This environmentally driven strategy resonated with Congress and other advocacy groups, breaking a legal and regulatory logjam that had existed for decades.

Today, health care entities must heed a variety of federal and state agencies in handling and discarding hazardous waste from prescription drugs or personal care products. The EPA and other agencies make resources available to health care workers as well as consumers to assist in proper drug disposal. Health care professionals, through their organizational

<table>
<thead>
<tr>
<th>U.S. Environmental Protection Agency*</th>
<th>National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention*</th>
<th>Occupational Safety and Health Administration, U.S. Department of Labor*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P list examples (acutely toxic)</strong></td>
<td><strong>Examples of drugs</strong></td>
<td><strong>Categories of drugs</strong></td>
</tr>
<tr>
<td>• Epinephrine base</td>
<td>• Azathioprine</td>
<td>• Antineoplastic cytotoxic agents</td>
</tr>
<tr>
<td>• Nicotine</td>
<td>• Bleomycin</td>
<td>• Antiviral medications</td>
</tr>
<tr>
<td>• Nitroglycerin†</td>
<td>• Chloramphenicol</td>
<td>• Anesthetic agents</td>
</tr>
<tr>
<td>• Warfarin &gt; 0.3%</td>
<td>• Chorionic gonadotropin</td>
<td><strong>Potential harm from drugs</strong></td>
</tr>
<tr>
<td><strong>U list examples (toxic)</strong></td>
<td><strong>Examples of drugs</strong></td>
<td><strong>Categories of drugs</strong></td>
</tr>
<tr>
<td>• Cyclophosphamide</td>
<td>• Cisplatin</td>
<td>• Cancer</td>
</tr>
<tr>
<td>• Daunomycin</td>
<td>• Cyclosporin</td>
<td>• Reproductive toxicity</td>
</tr>
<tr>
<td>• Diethylstibesterol</td>
<td>• Diethylstibesterol</td>
<td>• Organ toxicity</td>
</tr>
<tr>
<td>• Melphalan</td>
<td>• Estradiol</td>
<td>• Genetic disorders</td>
</tr>
<tr>
<td>• Streptozotocin</td>
<td>• Fluorouracil</td>
<td>• Birth defects</td>
</tr>
<tr>
<td>• Uracil mustard</td>
<td>• Medroxyprogesterone acetate</td>
<td></td>
</tr>
</tbody>
</table>

The EPA has 10 regional offices responsible for oversight in specific states, tribal areas, and territories. To help users obtain state-specific information, the EPA website offers a table of state-specific links for hazardous waste regulations. State regulations may permit additional significant fines. The EPA’s Enforcement and Compliance History Online dashboard allows users to analyze state activities and enforcement pertaining to hazardous waste. A review of the dashboard shows California and Missouri, for instance, are actively enforcing their regulations. In 2013, Walmart pleaded guilty to hazardous waste violations in both of those states and with the EPA. The fines totaled $82 million, with the EPA receiving $7.6 million, California $60 million, and Missouri $14 million.

CONCLUSION

LTCFs illustrate how broad practice changes were driven by health care professionals in response to waste issues and interagency contradictions that affected patient care. A similar effort by hospitals, combined with quality-of-care initiatives by The Joint Commission and other accreditation organizations, has also influenced these institutions’ drug waste and disposal practices.

In recent years, the initiative has shifted to the rule of law in addressing waste problems, led by the EPA under legislation passed by Congress. Health care organizations face increased financial risks as a result of steep penalties and other potential sanctions if they do not effectively manage drug waste to protect the environment. This environmentally driven strategy resonated with Congress and other advocacy groups, breaking a legal and regulatory logjam that had existed for decades.

Today, health care entities must heed a variety of federal and state agencies in handling and discarding hazardous waste from prescription drugs or personal care products. The EPA and other agencies make resources available to health care workers as well as consumers to assist in proper drug disposal. Health care professionals, through their organizational
leadership and/or P&T committees, and health care organizations, through their risk management committees, must ensure that these entities are using environmentally sound or prescribed methods for disposing of hazardous waste. Failure to do so can result in significant financial and legal actions against those who don’t follow the rules for prescription drug or personal care waste.

REFERENCES


