# Update on pharmaceutical waste disposal regulations: Strategies for success

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Trace pharmaceuticals have been identified and measured in our water supply as early as 1999, when a US Geological Survey study of over 1,000 sites found that 7% of public water supply samples and 14% of domestic water supply samples contained pharmaceuticals or hormones.[1] In 2018, a study found traces of oxycodone in seafood, specifically in Seattle-area mussels.[2] Compared to the rest of the world, the United States is one of the top countries in the number of pharmaceuticals found in drinking water.[3] Municipalities do not currently regulate water for pharmaceutical levels.[4] Furthermore, common filtration systems may not be adequately equipped to remove pharmaceuticals due to their unique chemical properties. While low levels of pharmaceuticals in water supplies currently pose an unlikely risk to human health, the long-term risks of continued long-term exposure, effects of pharmaceutical mixtures, and the potential for antibiotic resistance and drug tolerance are unknown. Health systems generate a significant portion of the pharmaceutical waste that is "sewered" into waste water, especially controlled substances (through efforts to render them irretrievable). The Environmental Protection Agency (EPA) recently published a new final rule on pharmaceutical waste disposal in an effort to simplify regulations and discourage sewering of all pharmaceuticals. Health systems must take responsibility to dispose of pharmaceutical waste in an environmentally friendly manner to avoid the continued contamination of water sources. The objective of this article is to highlight and identify the most significant changes in the EPA regulations that are relevant to health-system pharmacy and recommend practical ways to implement a successful program for pharmaceutical waste management.

**Current guidelines and regulations.** With several regulations governing different types of pharmaceutical waste, variations in regulations by state, and exclusion of pharmaceuticals from consideration under the Resource Conservation and Recovery Act (RCRA), the proper disposal of pharmaceutical waste is quite complex for health systems. The following section outlines all rules, regulations, and guidelines applicable to pharmaceutical waste disposal.

**EPA regulations.** EPA's authority to regulate pharmaceutical waste stems from 2 federal statutes. The 2008 RCRA regulates all hazardous waste. A pharmaceutical can be classified as "RCRA hazardous" if it is composed of a listed active ingredient or excipient or possesses a characteristic of ignitability, corrosivity, reactivity, or toxicity.[5] These "listed wastes" can be further classified as acutely hazardous (P-listed) or hazardous (U-listed) wastes, as demonstrated in Table 1. EPA has periodically released clarifications and exemptions of specific pharmaceuticals from hazardous classifications due to oversight of pharmaceutical inclusion within RCRA regulations. Due to this oversight, health systems need to individually review all medications on formulary by National Drug Code to identify hazardous pharmaceuticals. Incentivized to reduce the amount of P-listed (acutely hazardous) medication waste to minimize the impact of such waste on a site's generator status (ie, the volume of hazardous waste each generator produces in a calendar month determines which regulations apply to that generator) and corresponding requirements, several health systems separate acutely hazardous, hazardous, and nonhazardous waste. Perhaps even more burdensome, containers of acutely hazardous pharmaceuticals such as warfarin must be triple-rinsed to not count as acutely hazardous waste.

The Clean Air Act requires reductions in air pollutant emissions.[6] Several metals found in pharmaceuticals, such as selenium, mercury, chromium, and arsenic, are classified as hazardous air pollutants and thus cannot be incinerated if the compound's total organic content is less than 1%.

**DEA regulations.** Drug Enforcement Administration (DEA) regulations also impact waste disposal practices pertaining to controlled substance pharmaceuticals. DEA promulgated the 2014 Final Rule on Disposal of Controlled Substances, requiring any disposal of a DEA registrant's controlled substance inventory to be rendered nonretrievable and clarifying previous disposal methods of sewering or landfill disposal as no longer meeting the definition of nonretrievable.[7] This rule only applies to destruction of a registrant's inventory of controlled substances (such as the remaining milliliters of a multiple-dose vial); it does not apply to ultimate household users or to healthcare facility disposal of a partially administered syringe or single-dose vial. Thus,

**Table 1.** Subclassification of Pharmaceutical Waste by EPA Classification

| EPA Listing | Definition | Examples of Specific Agents |
|---|---|---|
| Acutely hazardous (P-listed) and hazardous (U-listed) waste | The P and U lists designate as hazardous waste pure and commercial-grade formulations of certain unused chemicals that are being disposed. For waste to be considered P- or U-listed waste, it must meet the following 3 criteria: 1) The waste must contain one of the chemicals listed on the EPA's P or U list. 2) The chemical in the waste must be unused. 3) The chemical in the waste must be in the form of a commercial chemical product. | P-listed: arsenic trioxide, warfarin<br>U-listed: chloral hydrate, selenium sulfide |
| Characteristic waste | Waste that contains a property that indicates that it poses a sufficient threat to deserve regulation as hazardous. These characteristics include toxicity, corrosivity, ignitability, and reactivity. Medications with these characteristics are classified by their respective D lists. | Aerosolized inhalers |
| Nonhazardous waste | Pharmaceutical waste that is not subject to EPA regulations because it does not meet EPA criteria for being hazardous | Metoprolol, vancomycin |

Abbreviation: EPA, Environmental Protection Agency.

several healthcare facilities and clinics continue to dispose of controlled substance waste via waste water. According to a 2016 global assessment of pharmaceuticals in the environment by the German Environment Agency, North America has the greatest amount of pharmaceuticals detected in drinking water, sewage and waste water treatment plants, and manure and soil—with analgesics and antibiotics being among the most frequently detected classes of pharmaceuticals.[8] DEA registrants can register as collectors of household pharmaceuticals for both controlled and noncontrolled pharmaceuticals. Registrants participating as collectors must destroy all collected pharmaceuticals following the nonretrievability standard and cannot sewer. However, collection bins and mail-back programs only pertain to ultimate users, meaning that controlled substances left in a hospital cannot be disposed of via a collection bin due to what is deemed the hospital's unlawful ownership of the controlled substance and should instead be handed to local law enforcement.[7] Table 2 includes a summary of regulations governing controlled substance waste disposal by type.

**OSHA regulations.** The Occupational Safety and Health Administration (OSHA) also regulates hazardous pharmaceuticals; OSHA oversight includes several non–RCRA hazardous drugs due to EPA's inability to list new pharmaceuticals as RCRA hazardous fast enough to match the rapid rate of new drug approvals.[9] Any pharmaceutical meeting the hazardous drug criteria set by the National Institute for Occupational Safety and Health (NIOSH) must meet requirements of OSHA, which has adopted the majority of *United States Pharmacopeia* (*USP*) chapter 800 guidelines on hazardous drug handling. Some states require incineration of all NIOSH-defined hazardous drugs. *USP* chapter 800 requires that all personal protective equipment (PPE) used in the handling of hazardous drugs—and recommends that other materials with trace contaminants—be placed in containers approved for trace contaminants.[10]

**Health department regulations.** State environmental and health departments regulate medical waste, which is defined as waste that may be contaminated by blood, bodily fluids, or other potentially infectious materials.[11] Some pharmaceuticals, such as human albumin, live vaccines, and immune globulin, are derived from human factors and meet this definition. These pharmaceuticals must be disposed of as biohazardous medical waste.

**Other regulatory agencies.** Three other agencies play lesser roles in regulating pharmaceutical waste disposal. The US Department of Transportation oversees the containerization and storage of toxic waste, requiring labelling with multi-colored placard labels and specific container markings.[12] The Atomic Energy Act regulates any pharmaceuticals with a radioactive component.[13] Lastly, FDA encourages patients to utilize drug take-back programs and maintains an FDA flush list of medications safe to flush.[14]

Together, these regulations, often overlapping for specific medications, result in a complexity of pharmaceutical waste management that few healthcare workers fully understand and comply with.

**2019 EPA final rule.** A final rule titled "Management Standards

**Table 2.** Disposal Options for Controlled Substances According to Owner, Hazardous Status, and Inventory Status

| Type of Controlled Substance Waste | Example | Disposal Options |
|---|---|---|
| Ultimate-user household controlled substance | Patient's leftover oxycodone pills | Collection bin |
| | | Take-back program |
| | | Mail-back program |
| | | Sewering (least preferable) |
| | | Remand to law enforcement |
| DEA registrant nonhazardous inventory | Remaining mL of fentanyl MDV | Secured destruction receptacle |
| DEA registrant nonhazardous pharmaceutical waste | Remaining mL of fentanyl SDV or syringe | Secured destruction receptacle |
| | | Sewering |
| DEA registrant hazardous inventory | Remaining mL of diazepam MDV | Secured destruction receptacle |
| DEA registrant hazardous pharmaceutical waste | Remaining mL of diazepam SDV | Secured destruction receptacle |
| Patient-owned controlled substance left in non-LTC or hospice healthcare facility | Patient discharged with discontinued controlled substance | Return to law enforcement |

Abbreviations: DEA, Drug Enforcement Administration; LTC, long-term care; MDV, multi-dose vial; SDV, single-dose vial.

for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine" was published by EPA on February 22, 2019, and includes 3 main sections: Part 261, the nicotine listing amendment; and Part 266 Subpart P, which includes the sections "Management of Hazardous Waste Pharmaceuticals" and "Reverse Distribution and Reverse Logistics."[15] EPA's intent with this new rule was not to newly apply RCRA regulations to hazardous waste pharmaceuticals but rather to change how hazardous waste pharmaceuticals are regulated under the RCRA moving forward. The remainder of this article will focus on outlining the first 2 sections of this new final rule. The latter section (Reverse Distribution and Reverse Logistics) will not be discussed in detail; however, it is important and should be reviewed by health-system pharmacists involved in determining the creditable status of pharmaceuticals and the reverse distribution process.

EPA focused on accomplishing several key goals in the new rule. The first was to design a waste handling and disposal strategy that is better suited to healthcare and the management of hazardous waste pharmaceuticals. The second was to prevent pharmaceuticals from entering waste water streams by reducing or eliminating the decades-old practice of flushing pharmaceuticals down the drain. EPA estimates that 2,000 tons of pharmaceuticals could be prevented from entering waste water streams annually once this rule is fully adopted and implemented. Additional goals of EPA's final rule are to provide clarity and reduce overlap of competing regulations that health systems are currently held accountable to. The new rule also creates consistency in how the RCRA applies to reverse distribution and removes nicotine replacement therapy (NRT) agents' previous classification as hazardous waste pharmaceuticals.

These key goals ultimately led to specific changes and implications for health-system pharmacy practice, including the following:

- Hazardous waste pharmaceuticals' impact on a facility's waste generator status
- Complete elimination of the flushing of hazardous pharmaceuticals managed under the RCRA
- A requirement to distinguish between creditable and noncreditable hazardous waste pharmaceuticals
- A choice to comingle most pharmaceutical waste or identify and segregate hazardous pharmaceuticals

**Amendment to nicotine listing.** Nicotine has historically been considered P-listed (acutely hazardous) waste by EPA, as designated by its P075 waste code. In the new final rule, bulk nicotine maintains its P075 waste code and continues to be listed as acutely hazardous waste. However, the amendment published in Part 261 concludes that NRT products such as patches, gums, and lozenges do not meet the regulatory criteria for acutely hazardous waste. Thus, FDA-approved nonprescription NRT products are no longer included under the P075 listing for hazardous waste. Nicotine patches, gums, and lozenges no longer need to be segregated as hazardous wastes and may be discarded as nonhazardous waste. Other unused formulations of nicotine, including electronic cigarette cartridges, nicotine vials, and spray and inhaler prescription nicotine products, will still be considered P075-listed agents when discarded.

Most states and territories have adopted and are held to the current rigorous regulatory standards of the RCRA

published in 2008. This act is currently comprised of standards that are more strict with regard to treatment of nicotine products than the newly published amendment to the nicotine listing. Because the new ruling is less stringent, states are not required to adopt the nicotine amendment, so institutions should seek guidance from their local state legislature to determine if and when updates to policies for treatment of NRT waste can be implemented.

**Management of hazardous waste pharmaceuticals.** In the new EPA final rule, Part 266 Subpart P includes many of the key changes that affect pharmacy operations. This section of the rule is considered more stringent than current RCRA regulations and therefore is not optional for state adoption, though states can always add stricter amendments. Hazardous waste pharmaceuticals must be managed in accordance to this section by all healthcare facilities and all reverse distributors except for very small-quantity generators that have a conditional exemption to opt out. Household generation of hazardous pharmaceutical waste is not regulated under this rule. After states adopt this new rule, all healthcare facilities must submit a one-time notification to the regional EPA administrator indicating that they are operating under Subpart P. Once notification is complete, a facility may then begin to update practice standards to take advantage of the potential benefits of this new rule.

A hazardous waste pharmaceutical is defined by EPA as "a solid medication waste that is listed or exhibits hazardous characteristics (i.e., toxicity, corrosivity, ignitability, reactivity)." This definition does not include medications that are legitimately used or have the ability to be reused. It also now excludes drug residue that may remain in containers once containing RCRA-listed pharmaceuticals. The mandate that RCRA containers must be triple-rinsed before disposal into municipal trash is no longer required for a P-listed (acutely hazardous) medication such as arsenic trioxide or physostigmine as long as it is fully administered and is not in a unique container type, such as a patch, inhaler, ointment, or cream. No P-listed pharmaceuticals fall in this category except for NRT patches (in states that do not adopt the federal classification of nonhazardous). Once its contents are fully administered, a container is no longer hazardous and can be disposed of via other disposal methods. Although EPA may no longer classify empty containers that once held hazardous pharmaceuticals as hazardous waste, trace chemotherapy waste–contaminated PPE, vials, and syringes should continue to be disposed of as hazardous waste due to *USP* chapter 800 and OSHA recommendations. Sharps bins are typically autoclaved due to their medical and biohazard waste contents and the potential for their contents to aerosolize. Because of the risk of aerosolization, empty containers with residual or trace amounts of incompatible waste (eg, zinc sulfate) or acutely hazardous pharmaceutical waste (eg, partial physostigmine syringes) must be disposed of as hazardous pharmaceutical waste for incineration and not within a sharps (or medical waste) bin.

Pharmaceuticals are specifically defined within the new EPA final rule, which is inclusive of any and all medications and medication types (prescription, nonprescription, dietary supplements, compounded, investigational), including partially filled containers. PPE that is physically contaminated with pharmaceuticals, clean-up material from pharmaceutical spills, and electronic nicotine delivery systems are also covered under EPA's definition of pharmaceutical. Excluded from the definition of a pharmaceutical are medical wastes, dental amalgam, and sharps containers. Any hazardous waste that does not meet the definition of pharmaceutical must continue to meet all applicable RCRA standards. This is an important differentiation for pharmacies, as there are several nonpharmaceutical products, such as isopropyl alcohol and various cleaning and disinfecting agents, that are RCRA-listed hazardous wastes that may be used in everyday practice. Pharmacy departments should review the ingredients and components of support chemicals against both the list of RCRA and state or federal incompatible-waste codes.

The final rule removes the impact of pharmaceutical waste on generator status determinations for healthcare facilities. While historically all healthcare facilities, reverse distributors, and industry manufacturers were regulated the same with regard to generation of hazardous wastes, including hazardous waste pharmaceuticals, the new rule eliminates the influence of a healthcare facility's amount of hazardous pharmaceutical waste produced on its generator categorization. An impact of this is that healthcare facilities are no longer required to track annual generation of hazardous waste pharmaceuticals and are no longer required to segregate hazardous from nonhazardous pharmaceutical wastes. Ultimately, this component of the new rule incentivizes facilities to manage all pharmaceutical waste, including non–acutely hazardous or nonhazardous waste, as if it were all hazardous. While this is highly impactful from a waste segregation and coordination perspective, some limitations still exist. Healthcare facilities must continue to segregate any incompatible, ignitable, and metal-bearing wastes due to other legislative restrictions outside the scope of RCRA previously mentioned in discussing the Clean Air Act. Containers that contain hazardous waste pharmaceuticals must be labelled with the phrasing "Hazardous Waste Pharmaceuticals" and are subject to a 1-year accumulation time limit. Manifest waste codes may be noted as "Pharm" instead of with the official agent-specific waste codes, with the exception of incompatible wastes. For any incompatible waste container that segregates incompatible metal-bearing and acutely hazardous waste, the established waste codes for each agent being stored must continue to be included on the container's manifest per Clean Air Act provisions and EPA's Land Disposal

Restrictions. Facilities must also continue differentiating pharmaceutical waste that is potentially creditable and destined for reverse distribution from all other forms of pharmaceutical waste.

**Sewer prohibition.** The new EPA rule directs that any hazardous waste pharmaceutical may not be sewered (ie, there can be no disposal down a drain and no flushing down a toilet). Hazardous wastes that are also listed as controlled substances by DEA are also subject to the sewer prohibition, which will lead to a key decision that pharmacy departments across the country will need to make regarding how to dispose of all controlled substance waste (hazardous and nonhazardous narcotic waste). While the scope of EPA regulation is limited to the management of hazardous wastes, EPA strongly discourages the sewering of any pharmaceutical, including nonhazardous pharmaceuticals, by any entity. For RCRA-listed hazardous pharmaceuticals that are also DEA-designated controlled substances ("RCRA/DEA controlled substances"), the new final rule clarifies an EPA exemption when a state formally adopts the new rule. This exemption clarifies that as long as they are managed in full compliance with the DEA and are rendered irretrievable (ie, there is no sewering or landfill disposal), these specific agents are exempt from EPA's pharmaceutical hazardous waste regulations. The sewer prohibition is considered more strict in comparison to any current state or federal law and went into effect in all states and territories on August 21, 2019.

**Reverse distribution.** Hazardous pharmaceuticals moving through reverse distribution and those determined to be either creditable or noncreditable are both considered pharmaceutical waste at a healthcare facility. However, in the new final rule EPA enables health systems to send potentially creditable hazardous waste pharmaceuticals to reverse distributors. Noncreditable hazardous pharmaceuticals cannot be sent to reverse distributors; therefore, facilities must put forth a good-faith effort to make a determination that such substances are potentially creditable before segregating potentially creditable from noncreditable hazardous pharmaceutical waste.

**Timeline and state adoption.** On February 22, 2019, the EPA final rule was published. The date of official authorization and enforcement was August 21, 2019. On this date, only the formal sewer ban prohibiting the sewering of hazardous pharmaceuticals, including hazardous controlled substances, went into effect for all states. For nonauthorized states (Iowa and Alaska), Subpart P and the nicotine amendment also became effective. For the vast majority of states and territories, an extended timeline for review, understanding, and adoption of Subpart P is provided. The date of formal adoption for authorized states is July 1, 2021, unless a statutory amendment is required, in which case the final rule must be adopted by July 1, 2022.

**Waste guidelines operationalization.** *Methodology for implementing compliance.* Understanding of both the federal- and state-level adoption timelines of the final rule, in addition to recognition of the areas requiring immediate compliance, is critical. While most states have until July 2021 to adopt this final rule, many states will likely follow the common trend of full adoption much sooner. The sewer ban is a non-negotiable, mandatory rule that went into effect first, in August 2019. Through review of the new rule and aligning the updated regulations with the numerous laws and acts promulgated by other agencies, a foundational understanding involving highly detailed interpretation of operational requirements for all waste management standards is necessary. Among all of the updates and changes, there are several requiring key decisions that can be used as a starting point to initiate discussions with health-system leaders. A working group consisting of interdisciplinary stakeholders including environmental services, nursing, clinic, supply chain, and finance personnel will be important in creating a strategy for how to practically meet these regulations through action planning, communication, and education. Pharmacy departments may be best suited to lead a health system's implementation of and education regarding the pharmaceutical waste disposal program. Environmental services staff may be best suited to collaborate with vendors, assess cost and maintenance implications, and incorporate pharmaceutical waste management into the larger institution's waste management program.

**Key decisions.** There are 3 key decisions that must be discussed by health-system leaders to ensure a consistent, standardized approach to pharmaceutical waste management. Conducting cost-benefit analyses and obtaining stakeholder feedback is critical for decision-making to ensure that anticipated costs are weighed against operational efficiencies. These decisions may also warrant a review and assessment of the most appropriate waste management vendor for an institution. The 3 key decisions are whether to separate or comingle controlled substance waste, whether to separate or comingle hazardous and nonhazardous pharmaceutical waste, and whether to separate or comingle trace chemotherapy and hazardous waste. For each of these decisions, the cost of hazardous waste incineration must be weighed against the benefits of simplicity, environmental protection, and space optimization.

*Standards interpretation and strategies.* Operationalizing pharmaceutical waste management requires an understanding of all standards, including recommendations and requirements for each step of the waste disposal process. Table 3 includes interpretation of all applicable pharmaceutical waste requirements along with corresponding strategy and implementation recommendations. The first step is to identify the different categories of wastes that need to be segregated. The simplest recommendation is to treat all pharmaceutical waste (including trace

**Table 3.** Key Implementation Recommendations Related to Hazardous Pharmaceutical Waste Disposal

| Waste Disposal Step | Interpretation of Requirements | Strategy and Implementation Recommendations |
|---|---|---|
| Identification of creditable and noncreditable waste | • Effective only when state adopts Part 266 Subpart P<br>• Only potentially creditable hazardous pharmaceutical waste can be sent to reverse distributor<br>• Noncreditable hazardous pharmaceuticals cannot be sent to reverse distributor<br>• Nonhazardous, noncreditable waste can be sent to reverse distributor if hazardous waste status is predetermined | • Segregate creditable from noncreditable pharmaceutical waste regardless of hazardous status (if comingling)<br>• Utilize report from reverse distributor to identify noncreditable waste<br>• Identify and educate staff on common reasons for noncreditable pharmaceutical waste (eg, repackaged, damaged, expired >1 year)<br>• Future software options may help facilitate differentiation |
| Identification of incompatible hazardous waste | • Metal-bearing pharmaceuticals may only be incinerated if the total organic carbon content is greater than 1%<br>• Waste codes on waste containers are required for wastes subject to Land Disposal Restrictions | • Identify all pharmaceuticals on formulary that may contain metals listed in 40 CFR Appendix IX to Part 261:<br>a. Check for updates to drug excipients using waste management vendor or internal environmental safety resources<br>b. Review "in list" annually<br>c. Review medications newly added to formulary at time of addition<br>• Visually place list of incompatible medications with waste code on each segregated bin to help identify contents that are not compatible |
| Identification of pharmaceutical waste disposal segregation requirements | • Empty containers are not considered hazardous if fully administered<br>• Can either segregate out hazardous waste or comingle all waste<br>• Incompatible pharmaceutical waste must be separated and labelled<br>• Controlled substance HWP must be nonretrievable and not sewered<br>• Pharmaceuticals with infectious risk must be disposed as biohazardous waste<br>• Trace chemotherapy waste–contaminated PPE must be incinerated (other materials recommended)<br>• Nonpharmaceutical hazardous waste must be labelled with waste codes | • Treat all pharmaceutical waste as hazardous, including trace chemotherapy waste, if practical and feasible<br>• Separate only incompatible and metal waste<br>• Sequester and transfer any nonpharmaceutical RCRA hazardous waste (eg, sterile alcohol, cleaning supplies) to institution's environmental services for central accumulation<br>• Create visual chart for waste segregation (Figure 1)<br>• Educate on "RCRA-empty" vs "non–RCRA-empty"<br>• Identify container and space requirements in all areas handling and disposing of pharmaceutical waste |
| Other key requirements | • 1-year accumulation time limit for noncreditable HWP<br>• Noncreditable HWP containers must be structurally sound, be compatible, and remain closed to prevent access<br>• Accumulation containers must be labeled "Hazardous Pharmaceutical Waste"<br>• Incompatible waste containers must be labeled with waste codes<br>• No labeling, storage, or accumulation standards on potentially creditable HWP<br>• Waste codes not required on manifest | • Ensure vendor-provided bins meet EPA and state DOT labelling requirements<br>• To avoid dating HWP accumulation start date, schedule routine vendor pickup of all containers in all areas, with documentation<br>• Document pharmaceutical waste as "Pharm" on manifest in lieu of using waste codes |

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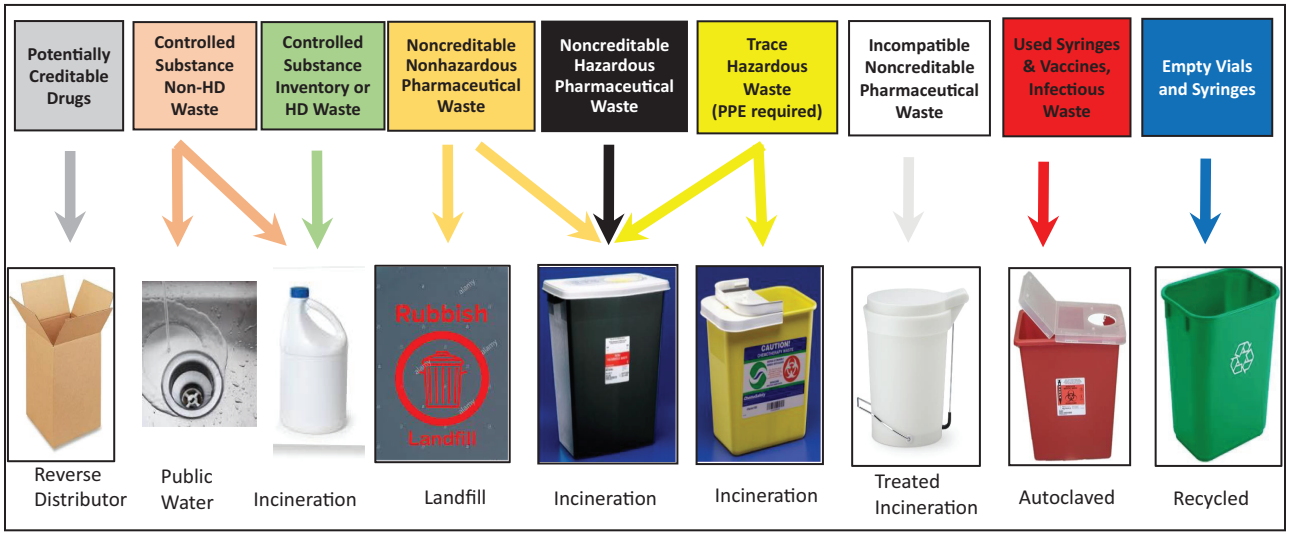
**Table 3.** Key Implementation Recommendations Related to Hazardous Pharmaceutical Waste Disposal

| Waste Disposal Step | Interpretation of Requirements | Strategy and Implementation Recommendations |
|---|---|---|
| Training | • All healthcare facility staff who handle HWP must be trained for proper waste handling relevant to their normal responsibilities<br>• Training can be part of routine onboarding<br>• No training documentation requirements for pharmacy or nursing staff<br>• RCRA training requirements for environmental safety and transporting staff still required | • Develop standard operating procedure and visual pharmaceutical waste management chart<br>• Identify departments and staff that handle and transport HWP<br>• Develop a new-hire onboarding and annual competency assessment for pharmacy staff in appropriate segregation of HWP following appropriate container standards<br>• Provide nursing and pharmacy staff education on appropriate controlled substance and HWP waste segregation |
| Record keeping | • All facilities must submit one-time notification of operating under Subpart P<br>• Not subject to biennial reporting requirements<br>• Must report any missing copies of manifest or rejected shipments<br>• May be asked to furnish additional reports concerning quantities and disposition of noncreditable HWP<br>• Keep copy of each signed manifest for 3 years | • Ensure environmental safety department of healthcare facility has routine process to check for rejected shipments or missing manifests<br>• Can utilize purchase data and dispense data if asked to quantify disposition of noncreditable HWP |

Abbreviations: DOT, Department of Transporation; EPA, Environmental Protection Agency; HWP, hazardous waste pharmaceutical(s); PPE, personal protective equipment; RCRA, Resource Conservation and Recovery Act.

chemotherapy waste) as hazardous, separating only incompatible metal-bearing waste, controlled substances, and potentially creditable waste, if that approach is practical and feasible for the health system. Nonpharmaceutical RCRA hazardous waste such as sterile alcohol and cleaning supplies should be sequestered and transferred to environmental services to be placed in the institution's central accumulation area instead of with pharmaceutical waste. Figure 1 includes a summary of disposal segregation requirements for each type of pharmaceutical. After identifying how each waste type will be segregated, institutions need to determine how to differentiate between potentially creditable waste, noncreditable waste, and incompatible waste. Most reverse distributors have routine reports that include which medications were not accepted for credit, including repackaged items, expired medications (outside a specific time frame), and opened or damaged items. Healthcare facilities should educate on common reasons and types of uncreditable products to help staff differentiate potentially creditable and noncreditable expired medications. While arsenic trioxide is the most well-known incompatible hazardous metal-bearing product that also needs to be segregated and labeled with waste codes, the health-system formulary should be reviewed to identify all metal-bearing compounds, and the appropriate waste management strategy for each newly added formulary medication should be reviewed at the time of formulary addition. A list of medications that are metal-bearing and incompatible should be placed on a specific bin to guide users on proper disposal. This list should be annually reviewed for updates to drug excipients, as many manufacturers are making efforts to remove metal components; for example, the mercury content of CroFAB (crotalidae polyvalent immune fab [ovine], BTG International) was recently removed. The training, record-keeping, and

**Figure 1.** Examples of visual signage for proper pharmaceutical waste disposal segregation; does not include nonpharmaceutical pharmacy waste (eg, sterile alcohol, cleaning supplies). HD denotes hazardous; PPE, personal protective equipment. Arrows denote suitable options for each waste type.




other key requirements outlined in Table 3 must also be considered.

**Conclusion.** While navigating pharmaceutical waste disposal regulations is still a highly complex process, EPA has helped to clarify and simplify the requirements and overlapping regulations for specific classes of pharmaceutical waste. The comingling and disposal of all pharmaceuticals as hazardous waste is the recommended strategy to reduce the environmental and public health impact that can result from water and landfill disposal. Doing the right thing may require changes in the cost structure for waste disposal, as well as changes to contracts with RCRA-certified disposal vendors, before healthcare facilities can optimally comply with the intended regulations.

## Disclosures

The authors have declared no potential conflicts of interest.

## References


1. Kolpin DW, Furlong ET, Meyer MT, et al. Pharmaceuticals, hormones, and other organic wastewater contaminants in U.S. streams, 1999–2000: a national reconnaissance. *Environ Sci Technol.* 2002; 36:1202-1211.
2. Rice J. Bay mussels in Puget Sound show traces of oxycodone. University of Washington Puget Sound Institute Web site. https://www.pugetsoundinstitute.org/2018/05/bay-mussels-in-puget-sound-show-traces-of-oxycodone/. Published May 9, 2018. Accessed December 17, 2019.
3. Weber FA, Bergmann A, Hickmann S, Ebert I, Hein A, Küster A. Pharmaceuticals in the environment—global occurrences and perspectives. *Environ Toxicol Chem.* 2015; 35(4):823-835.
4. World Health Organization. Pharmaceuticals in drinking-water. 2012. https://apps.who.int/iris/handle/10665/44630. Accessed November 17, 2019.
5. Resource Conservation and Recovery Act of 1976. 42 U.S.C. 82 §6901 -92.
6. US Environmental Protection Agency. *The Plain English Guide to the Clean Air Act.* Washington, DC: Environmental Protection Agency; April 2007.
7. US Drug Enforcement Administration. Disposal of controlled substances final rule. *Fed Regist.* 2014; 79(174):53520-53570.
8. German Environment Agency. *Pharmaceuticals in the environment: global occurrence and potential cooperative action under the Strategic Approach to International Chemicals Management (SAICM).* Berlin, Germany: German Environment Agency; September 2016. Report no. 002331/ENG.
9. US Department of Labor. Controlling occupational exposure to hazardous drugs. Occupational Safety and Health Administration Web site. https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html. Published February 2016. Accessed December 17, 2019.
10. Chapter 800: hazardous drugs—handling in healthcare settings. In: *United States Pharmacopoeia*. Rockville, MD: US Pharmacopoeial Convention; 2016;7721–7739.
11. US Environmental Protection Agency. Medical waste: disposal of medical sharps. https://archive.epa.gov/epawaste/nonhaz/industrial/medical/web/html/disposal.html. Last updated March 29, 2016. Accessed December 17, 2019.
12. Pipeline and Hazardous Materials Safety Administration, US Department of Transportation. PHMSA regulations. https://www.phmsa.dot.gov/phmsa-regulations. Last updated September 8, 2017. Accessed December 17, 2019.
13. Atomic Energy Act of 1954. 42 USC §2011–2021, §2022-2286i, §2296a-2297h-13 (August 30, 1954).
14. US Food and Drug Administration. Disposal of unused medicines: what you should know. https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know. Current as of February 1, 2019. Accessed December 17, 2019.
15. US Environmental Protection Agency. Final rule: management standards for hazardous waste pharmaceuticals and amendment to the P075 listing for nicotine. 42 USC §6912, §6921-6924. 84 FR 5816. Accessed February 22, 2019.