Untangling pharmaceutical waste requirements

There’s general agreement that keeping unused pharmaceuticals out of the nation’s water supply is a good idea. But figuring out how to comply with the tangle of regulations governing unused pharmaceuticals isn’t easy.

How intensely your facility is involved in managing pharmaceutical waste likely depends on how active US Environmental Protection Agency (EPA) enforcement is in your area, how aggressive your state regulators are, and how focused your organization is on green initiatives.

Though clinicians are used to flushing wasted medications or putting them in the trash, the EPA discourages these practices (sidebar).

The EPA says there’s evidence that pharmaceutical chemicals are finding their way into water supplies. Sewage treatment systems aren’t equipped to remove many of these chemicals. Though the EPA says there’s no evidence of adverse human health effects, having antibiotics, endocrine disrupters, and other drugs in the environment is cause for concern.

Federal regulations, despite their complexity, haven’t kept up. Only 5% of drugs are regulated under the EPA’s Resource Conservation and Recovery Act (RCRA), which hasn’t been updated since 1976—before many of today’s powerful drugs came on the market. The EPA is expected to propose a Universal Waste Rule in 2013 that will include pharmaceuticals and is intended to update and streamline regulations.

State activity

Meanwhile, much of the activity is on the state level, Cynthia Reilly, BS, of the American Society of Health-System Pharmacists (AHSP) told OR Manager. More than 20 states now have laws regulating pharmaceutical disposal. States can set stricter requirements than the federal government and enforce them with fines, she notes.

EPA inspections and fines vary by state. In some states, EPA regulators conduct more comprehensive restrictions, including checking ORs on pharmaceutical waste disposal. In others, they are not as thorough, though organizations are still account-

A challenge to manage

Developing a plan for managing pharmaceutical waste is a challenge. A hospital pharmacy can stock 2,000 to 4,000 different items. Only about 4% to 5% of these, or 100 to 200, are subject to RCRA, according to Practice Greenhealth, adding that another 10% should be managed as hazardous waste. If the EPA comes calling, failure to properly dispose of the drugs regulated as hazardous waste under RCRA can carry big penalties and fines.

Among difficulties are determining which drugs are “hazardous” from a regulatory standpoint, what quantities are relevant, and what disposal methods are acceptable. Wasted controlled drugs, such as narcotics, have to be managed under separate rules of the Drug Enforcement Administration (DEA).

The good news is that perioperative directors and managers don’t have to tackle the issue on their own, says Reilly. Usually, the facility has a team led by the phar-
macy or environmental services department that makes sure the facility is meeting standards and regulations, establishes processes, and provides staff training.

EPA’s best practices
The EPA offers a guide to the regulations and best practices in its 2010 Draft Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities. The guideline, which is not legally binding, has a flow chart and table on unused pharmaceutical management. The document covers RCRA definitions of hazardous waste and how these apply to pharmaceuticals.

Basic steps
The EPA suggests that a facility take these basic steps:
• Conduct an inventory of pharmaceuticals and unused pharmaceuticals to determine the amount the facility is disposing.
• Reduce unused pharmaceuticals by reviewing purchasing practices, using unit-dose dispensing, and related activities.
• Manage unused pharmaceuticals by identifying federal and state requirements, when possible sending them to a reverse distributor, and using EPA-recommended practices for disposal.
• Segregate waste for disposal to ensure regulations are met and to reduce costs.
• Train staff in proper disposal methods.

Hospital approaches
Two hospitals, one in Minnesota and one in Connecticut, described how they manage pharmaceutical waste, including in the operating room.

A community hospital’s program
North Memorial Hospital in Robbinsdale, Minnesota, has a yearly inspection by the EPA to determine whether all departments, including the OR, PACU, and same-day surgery, are managing all hazardous waste, including pharmaceuticals, according to the regulations, notes Michael Burke, CEH, CLLM, director of environmental services. He has been dealing with county, state, and federal regulators since 2005.

“These regulators are very serious,” Burke notes. During his first meeting with the regulator in 2005, he says, “She looked me in the eye and said, ‘Let me make it very

Why not to red bag pharmaceutical waste
As a best management practice, the EPA says unused pharmaceuticals should not be disposed of with biohazardous waste or as red bag waste.

Biohazardous waste is typically sterilized before disposal in landfills. But sterilization isn’t sufficient to destroy most pharmaceutical ingredients, the EPA notes. Also, during sterilization, wastewater may be generated and discharged through the sewer, reaching waterways.

The EPA’s goal is to keep pharmaceuticals out of the water.


Pharmacy waste regulations, guidelines

- The US Environmental Protection Agency (EPA) is proposing a federal Universal Waste Rule that is expected to include pharmaceuticals.
- The EPA presently enforces the Resource Conservation and Recovery Act (RCRA) of 1976 that regulates disposal of a list of hazardous drugs.
- The National Institute for Occupational Safety and Health (NIOSH) supports RCRA with an expanded list of hazardous drug agents.
- The American Society of Health-System Pharmacists (ASHP) has guidelines on Handling Hazardous Drugs and has provided input to the NIOSH list of hazardous drugs and to the EPA on the proposed Universal Waste Rule.
- The Joint Commission requires hospitals to have a hazardous materials and waste management plan.
clear to you, I have the authority to not only fine you but to personally throw you in jail.” “Anyone representing an organization that knowingly dumps hazardous material improperly can be held accountable through both jail time and fines, Burke says.

North Memorial incinerates all hazardous and nonhazardous waste, though this is more expensive than other types of disposal.

“We made the choice for incineration because we wanted to keep it out of the ground water,” says Burke.

Disposal bins are color coded:

• black bin: hazardous pharmaceutical waste
• white bin: nonhazardous waste
• red bin: infectious biomedical waste
• sharps container: all sharps.

Each type is incinerated according to its hazard level. Incineration of nonhazardous waste is one-fifth the cost of hazardous waste disposal, and proper segregation reduces costs.

With education and proper segregation, North Memorial’s OR alone reduced its costs for incinerating hazardous waste by about $175,000 in the first year, says John Simpson, vice president of hazardous waste sales for Stericycle, a medical and pharmaceutical waste disposal company based in Lake Forest, Illinois.

An academic medical center’s approach
At Yale-New Haven Hospital, wasted drugs can no longer be poured down the drain. All pharmaceutical waste is incinerated, says Jodi Sherman, MD, assistant professor of anesthesiology and environmental compliance officer at Yale University School of Medicine, New Haven, Connecticut.

She says regulators are concerned about making sure all drug-filled syringes on the anesthesia cart are properly labeled and locked up between cases. Also, anesthesiologists can no longer put a label on an empty syringe in anticipation of having to draw up a drug in an emergency. The EPA considers this a hazard, although she says having prelabeled syringes in case of emergency “saves precious time.”

“Permitting the preparation of syringes in advance is an intermediate step that saves time and waste but, unfortunately, is no longer permitted,” she says.

Regulators have also cracked down on multi-dose vials.

“We are no longer allowed to use multi-dose vials on more than one patient,” says Dr Sherman, resulting “in a tremendous amount of waste.”

Where these vials are discarded depends on if they are listed as hazardous (P- or U-listed) under RCRA (sidebars).

• P-listed drugs are considered acutely hazardous. Examples in the OR are epinephrine, phentermine, nicotine.

### Common P-listed pharmaceuticals

<table>
<thead>
<tr>
<th>EPA code</th>
<th>Agent</th>
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<tbody>
<tr>
<td>P012</td>
<td>Arsenic trioxide</td>
<td>P081</td>
<td>Nitroglycerine</td>
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<td>P042</td>
<td>Epinephrine</td>
<td>P204</td>
<td>Physostigmine</td>
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<td>P046</td>
<td>Phentermine</td>
<td>P188</td>
<td>Physostigmine salicylate</td>
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<tr>
<td>P075</td>
<td>Nicotine</td>
<td>P001</td>
<td>Warfarin &gt;0.3%</td>
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### Examples of U-listed pharmaceuticals

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<tr>
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<td>U035</td>
<td>Chlorambucil</td>
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<td>U188</td>
<td>Chloroform</td>
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<td>U058</td>
<td>Cyclophosphamide</td>
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<td>U059</td>
<td>Daunomycin</td>
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<td>U075</td>
<td>Dichlorodifluoromethane</td>
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<td>U089</td>
<td>Diethylstilbestrol</td>
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<td>U122</td>
<td>Formaldehyde</td>
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<td>Hexachlorophene</td>
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<td>Mitomycin</td>
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<td>U182</td>
<td>Paraldehyde</td>
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<td>U188</td>
<td>Phenol</td>
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<tr>
<td>U200</td>
<td>Reserpine</td>
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<td>U201</td>
<td>Resorcinol</td>
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<tr>
<td>U205</td>
<td>Selenium sulfide</td>
</tr>
<tr>
<td>U206</td>
<td>Streptozotocin</td>
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<td>U121</td>
<td>Trichloromonofluoromethane</td>
</tr>
<tr>
<td>U237</td>
<td>Uracil mustard</td>
</tr>
<tr>
<td>U248</td>
<td>Warfarin &lt;0.3%</td>
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nephrine and nitroglycerin. These are disposed of in black bins.

- U-listed drugs are considered hazardous but not acutely hazardous. These are segregated into purple and white bins (though these colors are not standardized among hospitals).

Some hospitals have a combination sharps/pharmaceutical bin, which is usually purple, she says. Specific requirements must be met for disposal of this combined waste stream.

States differ in their requirements for disposal of vials that are not sharp and ampules that have to be broken open and are sharp. In Connecticut, broken ampules go into the sharps container, and vials with 3% or less of a drug remaining in them can go into the regular trash—as long as the drug is U-listed and not P-listed.

“Whether we are safe throwing these drugs away because there’s less than 3% left, I don’t have an answer,” Dr Sherman says.

### The EPA’s Universal Waste Rule

The EPA’s long-awaited Universal Waste Rule is expected to be issued for comment in 2013. The agency says it plans to add pharmaceutical wastes to the rule, which would apply to hospitals, physician offices, ambulatory facilities, and other healthcare organizations. The rule is expected to propose that certain kinds of pharmaceutical waste could be disposed of as part of “universal waste” that also includes items such as batteries and items containing mercury. The agency says its intent is to streamline current regulations to help ensure that more pharmaceutical waste is managed properly and to reduce the regulatory burden. The details remain to be seen.

—Judith M. Mathias, MA, RN

### References

- Environmental Protection Agency. Pharmaceuticals and personal care products. Frequent questions. www.epa.gov/ppcp/faq.html