The right prescription
Managing pharmaceutical waste is environmentally correct and the law

The primary axiom of health care organizations is “First, Do No Harm.” With much attention focused on medication safety and quality assurance, it is equally important that we focus attention on not causing harm downstream by the inappropriate disposal of pharmaceutical waste.

Pharmaceuticals are potent agents for good, reducing health care costs by keeping patients out of hospitals and emergency rooms and by preventing the deterioration of chronic conditions. But this sword has two edges—the same drugs that heal one person may harm another if taken inappropriately or inadvertently.

Pharmaceuticals are now being considered “emerging contaminants” by the U.S. Geological Survey (USGS). A study published in March 2002 called “Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance” and available on the Web at http://pubs.acs.org/cgi-bin/jitextd?estag/36/6/html/es011055j.html, the USGS found multiple drugs in a variety of streams sampled around the country. They were present only in minute amounts, but coupled with the increasing understanding of the devastating effects of a class of chemicals known as endocrine disruptors, which mimic the body’s hormones or block their activity, and you have a recipe for “harm.”

The gatekeeper
The ES manager is the gatekeeper of every disposed item managed by the facility. He or she needs to know how the organization is disposing of drugs, then assist the organization in managing the disposal in an environmentally responsible manner.

In addition to concerns about drugs entering the water supply, ES managers have an “up close and personal” reason to focus on pharmaceutical waste management. The Resource Conservation and Recovery Act (RCRA), enforced by the U.S. Environmental Protection Agency (EPA) and state environmental agencies, defines a number of pharmaceuticals as hazardous chemical waste.

These items cannot legally be disposed of through sewering, municipal landfills, red sharps containers or even as chemotherapy waste. They must be identified and segregated as hazardous chemical waste, similar to laboratory or radiology waste, and managed under strict storage, labeling, manifesting, transporting and disposal regulations.

With respect to waste pharmaceuticals, two lists of chemicals—the P- and U-list—must be examined for therapeutic agents in the pharmacy that may potentially be discarded:

• P-listed waste. From the EPA's perspective, these hazardous chemical wastes are the worst and include such notorious toxins as arsenic, cyanide salts and strychnine. The P-list also includes
chemicals used therapeutically such as epinephrine, nicotine and warfarin (in concentrations over 0.3 percent).

- **U-listed waste.** These chemicals are not considered quite so disastrous to human health and the environment when improperly managed as waste, but are still highly regulated. All U-listed chemicals that are also pharmaceutical agents are listed for reasons of toxicity and include such commonly used drugs as cyclophosphamide, lindane, mitomycin C and selenium sulfate.

If a drug is the sole active ingredient of the product and is named on the P-list as acutely hazardous, or on the U-list as toxic, that item is hazardous waste when discarded.

RCRA also provides for the management of chemical formulations as hazardous waste if they exhibit ignitability, toxicity, corrosivity or reactivity. These are harder to identify because the individual drug product must be evaluated.

For instance, if a liquid preparation has 24 percent or more alcohol and a flash point of less than 140 degrees F, it is considered ignitable. Toxic waste includes drug products containing mercury preservatives, barium sulfate enemas and other heavy-metal containing products. Corrosivity applies to highly acidic (pH less than or equal to 2) or highly basic (pH greater than or equal to 12.5) aqueous solutions. The only reactive drug is nitroglycerin, which is explosive in pure form. In August 2001, the EPA excluded nitroglycerin tablets, capsules and other nonignitable dosage forms from regulation because they aren’t reactive, but not all states have adopted this exclusion yet.

While identifying and segregating these items can seem daunting, a simple start can be made with the P- and U-list. For more on RCRA, go to www.h2e-online.org/tools/chem-pharm.htm and review the article “Bad Medicine: Managing Drug Waste Liabilities.”

**How is your facility doing?**

How are waste pharmaceuticals being disposed of by your facility? Hopefully the pharmacy department is using the services of a qualified reverse distributor to ship outdated pharmaceuticals back to the manufacturers for credit. Not only does this bring thousands of dollars back into the pharmacy budget each year, it enables all outdated drugs to be shipped out as products, not as wastes.

This significantly reduces the volume of drug waste generated by your facility. However, it’s important to ascertain that only outdated drugs are being shipped to the reverse distributor, not unused IVs or other “waste-like” items.

To help your organization choose a reverse distributor that manages the waste it generates appropriately, you might refer to the Returns Industry Association’s Web site at www.returnindustry.com.

Run by the trade group for pharmaceutical reverse distributors, the site lists the minimum federal regulatory standards expected of reverse distributors.

However, there are also many other potential sources of drug waste, such as spills and breakage, IV preparations, unused IVs, partially filled vials and syringes, and patients’ personal medications. These waste drugs can occur anywhere in the organization. As Fig. 1 illustrates, they are most likely either being sewered, or disposed of in chemo waste or red sharps containers.

There are many problems with these disposal methods. They include:

- **Sewering.** Any drugs considered hazardous chemical waste by the EPA cannot be sewered under any conditions. Though they’re not considered hazardous waste under RCRA, antibiotics may also cause problems. ES managers should check with their local waste treatment plants to find the loads of antibiotics, hormones and other organic chemicals that can be handled. Many health facilities have decided not to dispose of antibiotics through sewerage as a best management practice. Not only can antibiotics interfere with the microbial activity of the treatment plant, there is growing concern that such practices encourage the evolution of resistant strains of bacteria.

- **Chemo waste containers.** If it’s called chemo waste, doesn’t it make...
sense that chemotherapy drugs can be disposed of in those white or yellow sharps containers? Unfortunately, the name is a bit of a misnomer. If you follow the pathway of the chemo waste containers, you will see they are disposed of as regulated medical waste. Hopefully, they are incinerated, although in some cases they have simply been autoclaved or microwaved, then shredded and landfill.

While autoclaving and microwaving are adequate for disinfection, the chemotherapy molecules stay relatively intact, and can potentially leach into the groundwater. Depending on how the autoclave is vented, the potential may also exist for vaporization of the molecules into the surrounding area. Even regulated medical incineration may not always destroy these molecules.

From a regulatory perspective, seven chemotherapy drugs are listed by the EPA as hazardous waste and cannot be treated by a regulated medical waste facility. Unfortunately, the EPA regulations have not kept up with the pharmaceutical industry and many more chemotherapy drugs are just as hazardous and yet are not regulated under RCRA. So one option is to consider all chemotherapy residue and bulk wastes as hazardous chemical waste as a best management practice.

Another compelling reason to do this is the waste acceptance protocol of your regulated medical waste disposal vendor. It is very likely that in your contract, the vendor spells out that acceptable chemo waste includes only “empty” vials, syringes and I.V.s. According to the EPA, these items are empty only when everything has been removed that can be removed and there is not more than 3 percent left inside.

You may run into some dispute about this from the pharmacy department, since a standard was set years ago that misinterpreted the 3 percent to mean 3 milliliters, and neglected the need to withdraw all liquid from vials.

• **Red sharps containers.** Finally, regulated medical waste disposers are adamant that drugs should not be placed in red sharps containers unless, of course, it is a syringe that has been contaminated as infectious waste.

Nonhazardous pharmaceutical waste can be collected in beige sharps containers and labeled as pharmaceutical waste, rather than infectious waste. This enables the disposer to audit the shipment for the presence of hazardous waste and preferably to incinerate it.

**What to do?**

So what do you do with residue chemotherapy agents and other hazardous pharmaceutical wastes that can’t be disposed of through the conventional means? You need to establish a new waste stream.

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Containers for the new hazardous waste stream should be labeled “RCRA Hazardous Waste Toxic” and should be hard plastic, non-red containers with covers that can be remotely opened and closed. They should be placed in strategic but secure areas in the pharmacy department, OR, ER, ICU/CCU, oncology units and any other departments that may generate wastes that are considered hazardous under RCRA.

The pharmacy department may also need a second container labeled “RCRA Hazardous Waste Ignitable” because any drug product containing 24 percent or more alcohol becomes hazardous waste when discarded. Fig. 2 illustrates these three new waste streams and Fig. 3 integrates these waste streams into the common existing waste streams and describes the contents of each one.

How often should these containers be transferred and where should they go? The timeframe for transferring the container out of the units or departments is dependent on volume because the law allows up to 65 gallons of total hazardous waste and one quart of P-listed waste to be held at a “satellite accumulation site.”

Space restrictions and practicality will necessitate transferring these containers at least monthly in low waste generation areas and more often in higher generation areas, such as the pharmacy. The entire container should be transferred to the area in which you currently store other hazardous wastes, such as waste formaldehyde, xylene, batteries, laboratory chemicals, pesticides, etc.

This should be a secured area with limited access and be considered your hazardous waste “storage accumulation area.” If you do not already have such an area designated, try to find an area away from normal traffic flows that can be locked and is large enough to contain several 55-gallon drums if needed.

How do you manage the disposal of these hazardous wastes? Unless you are a large facility and have personnel trained in the ways of RCRA and the U.S. Department of Transportation, consider contracting with either a regional hazardous waste broker or a national hazardous waste disposer that offers on-site lab-packing, labeling, manifesting and transportation services.

Either way, these wastes are tracked “cradle to grave” with very specific and stringent procedures. Some of these vendors offer transfer services at each department, eliminating the need for you to train your employees as required by OSHA under the Hazardous Waste Operations and Emergency Response Standard (HAZWOPER). More information on HAZWOPER is available online at www.osha.gov/SLTC/ets/hazwoper.html.

When the federally permitted RCRA Treatment, Storage and Disposal Facility (TSDF) receives the hazardous waste, your facility will get a signed copy of the five-part manifest verifying this receipt. The TSDF often has a year to incinerate the waste because of the need to blend it with compatible hazardous wastes, but most facilities accomplish incineration within a month or two. You should also receive notification once the incineration has been completed.

By learning more about this important waste stream and how to bring your organization into compliance, you are accomplishing several goals. They include:

- Contributing to good risk management by reducing the chance for corporate fines and penalties and negative publicity;
- Demonstrating to all employees and the community at large that your organization takes its environmental responsibility seriously, both internally and in the broader sense; and
- Positioning your organization to move forward with a much greater understanding of chemical hazardous waste issues, should you ever be faced with a chemical disaster scenario.

As an added bonus, if you are within one year of your JCAHO accreditation review, you can use all activities in this respect as a performance improvement initiative.

Make the most of it!

You now know more about this issue than most health care professionals. This is your area of expertise—make the most of it!

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