

Q&A

With Charlotte A. Smith, RPh, MS, HEM,
President of PharmEcology Associates, LLC

# Pharmaceutical Waste Management

## Regulatory Compliance and Best Practices

**Q: What changes have been made to the EPA's classification for epinephrine salts?**

**A**: On October 15, 2007, the EPA issued a memorandum stating that epinephrine salts were not noted in the original regulation and, therefore, are not and never have been classified as P-listed waste, unless the drug exhibits characteristics of hazardous waste, such as ignitability. This makes a huge difference to hospitals, because epinephrine caused many hospitals to designate as large-quantity hazardous waste generators. Due to the insolubility of epinephrine base, all finished dosage forms used in hospitals will be either hydrochloride, bitartrate, or borate salts of epinephrine. Epinephrine base is still classified as hazardous waste, but would only occur as a bulk powder.

Even though epinephrine salts are no longer classified by the EPA as hazardous waste, hospitals still need to document the amount of P-listed waste they generate each month, if they want to remain a small-quantity or a conditionally exempt small-quantity generator. The good news is they have a shot at it. The bad news is they have to document and segregate their P-listed waste. If you are already a large-quantity generator, you may want to remain so, as you can generate as much P-listed waste as you want. As a small-quantity generator, you can only generate 2.2 pounds or 1 kilogram of P-listed waste per calendar month and you must be able to document that.

**Q: Have the state regulatory agencies followed the EPA's suit regarding epinephrine?**

**A**: Hospitals, for safety's sake, should check with their state regulatory agencies before making any changes to their hazardous waste policies, as some states have already adopted the EPA's ruling, while others are still considering it. Call your state regulatory agency and ask to speak to a member of their hazardous waste technical assistance staff.

**Q: What changes have been made with regards to nitroglycerin?**

**A**: Nitroglycerin is certainly still regulated, however, in 2001, the federal HWIR – or Hazardous Waste Identification Rule – excluded weak medicinal nitroglycerin from P-list categorization since it is no longer reactive. Dilute nitroglycerin – the type we use in the pharmacy – does not exhibit reactivity. Some states have yet to formally adopt this federal rule. So, again, it's extremely important to check with your state regulatory agencies on this matter.

**Q: How should hospital pharmacies handle used and unused nicotine patches?**

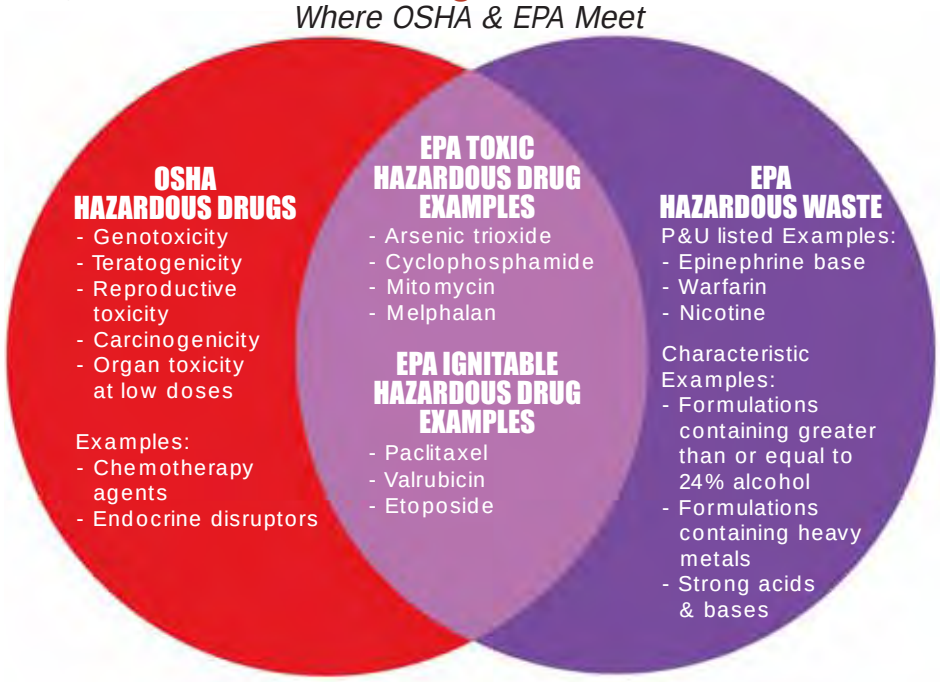
**A**: There is still a lot of ambiguity surrounding nicotine patches. Because the P-listed designation only applies to unused items, a used nicotine patch is not defined as hazardous waste by RCRA. Some states, like Minnesota, designate used nicotine patches as lethal waste and require special handling for them. It is our understanding that the EPA designates unused nicotine patches as P-listed waste, and typically, a pharmacy's reverse distributor will handle its unused patches. Since a high percentage of drug remains in the used patch, a best practice would be to manage it as hazardous waste.

**Q: What best practices should pharmacists keep in mind when managing pharmaceutical waste?**

**A**: First of all, if RCRA classifies a pharmaceutical as hazardous waste, it must be disposed of as such. Beyond this, there are a variety of agents that should, in a best-practice model, be treated as hazardous waste. On www.pharmecology.com, we have posted a list of criteria for products that, while not technically hazardous per RCRA, should be managed as hazardous waste due to their potential to cause harm. (See sidebar on page 8 for this list).

We also recommend that other pharmaceuticals be managed as non-

**Figure 1 Hazardous Drugs vs. Hazardous Waste**
*Where OSHA & EPA Meet*



## Best Practice Recommendations

Due to their potential to cause harm, products meeting the following criteria should be treated as hazardous waste under a best practice model for pharmaceutical waste management. This classification indicates that professional judgment would encourage the management of a waste as hazardous even if it does not meet the technical definitions of hazardous waste under RCRA.

- Formulations containing a P- or U-listed drug that is not the sole active ingredient
- Formulations referenced in the NIOSH Hazardous Drug Alert Appendix A, the OSHA Technical Manual Section 6, Chapter 2, Appendix VI: 2 -1, and the US Department of Health and Human Services National Toxicology Program's Report on Carcinogens (11th Edition)
- Chemotherapy agents not already listed as RCRA hazardous
- Additional drugs meeting OSHA or NIOSH criteria
- Drug formulations with LD50s at or below 50mg/kg
- Endocrine disruptors
- Bulk powders
- Vitamin or mineral preparations that may fail the toxicity characteristic due to chromium, selenium, or cadmium for which there is inadequate data at this time

(Information courtesy of PharmEcology Associates, LLC)

hazardous pharmaceutical waste and, therefore, incinerated at a regulated medical waste incinerator or a municipal incinerator. Both of those types of facilities need a permit to handle non-hazardous pharmaceuticals. Pharmacies should move away from drain and landfill disposal of pharmaceutical waste. The EPA has recently released its 2008 Effluent Guidelines (www.epa.gov/fedrgstr/EPA-WATER/2007/October/Day-30/w21310.pdf), so it looks like the days of disposing of pharmaceuticals in the sewer system are coming to a close.

That said, pharmacy's biggest opportunity to reduce its impact on the environment and the amount of pharmaceutical waste it generates is to tighten its inventory control practices. Simply put, expired medications will become pharmaceutical waste, and even if they are not disposed of at your facility, your reverse distributor, the manufacturer, or your waste management services provider will have to incinerate them down the road. So anything pharmacy can do to control its inventory can be a major contribution to reducing the environmental impact of pharmaceutical waste, while saving the pharmacy money.

**Q: To ensure effective pharmaceutical waste management, what should pharmacists do when a new drug is added to the formulary?**

**A**: They need to examine the drug to determine whether or not it meets the criteria for hazardous waste. The same applies for off-formulary drugs, as well as items ordered by other departments, like radiology and respiratory therapy, and medication samples from pharmaceutical sales representatives. Outpatient clinics should certainly understand the liability that goes along with accepting medication samples and, whenever possible, require vouchers from sales reps instead of samples. If medication samples are expiring before being dispensed to patients, you are stocking too many samples and should consider restricting the number you will accept in any location. Some hospitals even restrict samples to formulary items.

Patients' personal medications create an interesting situation, because federally and at the state level, there are no regulations for in-home hazardous waste disposal. However, once those drugs are in a hospital, they may be subject to state-specific regulations for pharmaceutical waste management. Some states exclude patients' own medications from disposal regulations, but require so much documentation that it may be simpler to categorize and dispose of those drugs as hazardous waste. Furthermore, hazardous waste disposal is very secure and can satisfy HIPAA requirements for protecting patient information.

**Q: What other drugs should pharmacists keep their eyes on when developing their pharmaceutical waste management program?**

**A**: I recommend treating investigational drugs as hazardous waste, just to be on the safe side. Furthermore, gene therapy is highly bio-hazardous and should be very care-

*Continued on page 11*

*Continued from page 8*

fully handled and ultimately incinerated as regulated medical waste.

**Q: Once best practices have been established for waste management, how can pharmacy leadership ensure staff follows the policy?**

**A**: Initial and annual training are a must. It can still be tough, because pharmacies may have a high level of employee turnover, but there should be some sort of annual or semi-annual audit in place. Some institutions perform unannounced safety "walk-arounds" to evaluate compliance with these kinds of policies. This practice can encourage departments to maintain compliance in between their regularly scheduled audits.

**Q: What should be evaluated during those audits?**

**A**: First, make sure all of the drugs currently held in inventory are categorized, particularly those that have recently been added to the formulary. Also be sure a solid process is in place for reviewing new drugs that come into the system and that someone is held accountable for performing that review. Make sure all of pharmacy's shelves are properly labeled if they contain a drug that needs to be managed as hazardous waste, and also make sure those agents are properly labeled so they can be handled appropriately in the pharmacy and on the nursing units. Keep in mind that some agents – such as some TPN ingredients – may qualify as hazardous waste only prior to being diluted, and will not need to be handled as such on the nursing unit. Document that the necessary calculations were performed and that sound decisions have been made for handling these types of agents. If you have chosen to categorize drugs as hazardous waste in your pharmacy information system, be sure all the appropriate drugs are highlighted in the software. Lastly, work with your environmental services and safety departments to ensure that appropriate waste management vendors and waste containers are being used by the pharmacy. Those are pharmacy's key responsibilities in pharmaceutical waste management.

*Continued on page 26*

# Cover Story

*Continued from page 24*

view utilization in real time, on a daily basis, and report any issues that might interfere with utilization.

In addition, the pharmacy management team should review the BCMA system data to determine if there are any particular medication issues affecting the system. At LVHN, the pharmacy directors and associate directors review this data on a monthly basis, looking for medications with a 0% scanning rate. In these cases, a medication may have arrived without a bar code or the preprinted bar code may not have been entered into the system. If a manufacturer changes a product's bar code or a new brand of a product is purchased and not activated in the system, the nurse will be unable to scan the product and find a match. Continuous monitoring of such situations has made BCMA a success at LVHN. The hospital's overall bar code usage is nearly 97%, with pediatrics at 94%, the NICU at 95%, and the pediatric intensive care unit at 97%.

## Conclusion

Bar code technology presents today's hospitals with a variety of methods for improving pediatric medication safety. That said, BCMA does not take the place of a health care professional's critical-thinking skills; it merely adds to the technological safety net we hope to surround ourselves in. We must remain vigilant and carefully monitor practices at our facilities, in order to safely administer care to our pediatric patients. ■

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| Vestara | 15 | 65 |

# Waste Management

*Continued from page 11*

**Q: Is the Joint Commission surveying hospitals' pharmaceutical waste management practices?**

**A**: Yes. Depending on the surveyor's familiarity with these issues, they may very well ask to see your pharmaceutical waste management policies and procedures. Using the tracer methodology, they may follow a drug through your medication use process and evaluate your disposal of it. While pharmaceutical waste management is not specifically or overtly noted in the Joint Commission's medication management standards, it is covered under the Environment of Care Standard 3.10, which requires hospitals to have a hazardous materials and waste management plan.

**Q: OSHA is updating the NIOSH list of hazardous drug agents. How will the expanded list affect pharmaceutical waste management in hospitals?**

**A**: There is general confusion over this issue, because there is very little overlap between NIOSH hazardous drugs and EPA hazardous waste. (See Figure 1.) OSHA, which identifies occupational hazards, uses a separate list of criteria from the EPA, which identifies environmental hazards. Part of the problem is the EPA didn't keep up; there are 100 chemotherapy agents that should be classified as hazardous waste that aren't.

**Q: How will this issue resolve itself?**

**A**: The health care profession has to step up to the plate and use best practices to manage NIOSH-listed hazardous drugs – or at least the chemo agents – as hazardous waste. I know a chemotherapy nurse who had three miscarriages and still wonders if handling those agents didn't have something to do with it. We were very cavalier in the old days, but it is much better for health care professionals to be aware of the risks presented by the improper handling of hazardous drugs. ■

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