Pharmaceutical waste generators such as hospitals will be subject to new regulations from both federal and state authorities that will require them to alter their current disposal practices.

Drug interactions

Pending pharma waste regulations

BY JOHN KELSEY

A handful of regulatory rulings from the Environmental Protection Agency (EPA), the Drug Enforcement Administration (DEA) and some state environmental regulatory agencies could fundamentally affect how health care organizations handle their pharmaceutical waste.

All have the potential to impact organizations that generate pharmaceutical waste because they carry environmental, operational and financial implications.

Following are highlights of these regulations, how they relate and what their effects may be. It is not a comprehensive review and environmental services professionals are advised to study source materials from the agencies.

Amalgamation of rules

The proposed rules do not perfectly interlock because the EPA and the DEA have different objectives; and some states have authorizations that are more stringent than federal rules and therefore supersede federal law. For instance, the EPA is looking at reclassifying hazardous pharmaceutical wastes to the Universal Waste Rule (UWR) while the DEA is considering revising rules on the disposal of controlled substances from nonregistered ultimate users. Additionally, several states either already have authorizations or are considering authorizations that will affect pharmaceuticals and may govern how the federal regulations are implemented within their jurisdictions. All of these activities are happening essentially simultaneously. The EPA's comment period ended March 3, 2009; the DEA closed its solicitation for information on March 23, 2009; and the states are at various stages based on their administrative and legislative calendars.

EPA amendment

The EPA proposal would amend the Universal Waste Rule 40 CFR Part 260, 261, 264, 265, 268, 270 and 273 to add pharmaceuticals that are currently classified as hazardous wastes under the Resource Conservation and Recovery Act (RCRA). This means that a lower standard of regulation would be applied to the most hazardous pharmaceuticals. This will reduce generator requirements somewhat by providing simpler handling, while ensuring that the pharmaceutical universal waste would still be managed properly at a RCRA incinerator either directly from the generator or through a universal waste (UW) handler.

By the agency's reckoning, this would affect more than 600,000 individual facilities in the United States, including approximately 40,000 retail pharmacies and over 7,000 hospitals. Included in this group are physicians, dentists, other health care practitioners, outpatient care centers, ambulatory health care services, residential care facilities, veterinary clinics and reverse distributors.

The rule change would apply to "pills or tablets, medicinal gums or lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compounded solutions, chemotherapy drugs, vaccines, allergenics, medicinal shampoos, antiseptics and medicinal dermal patches and any delivery devices with the primary purpose to deliver or dispense a chemical product,

vaccine or allergenic."

The rule will include 31 P-Listed and U-Listed pharmaceutical wastes, as well as pharmaceutical wastes that are not listed but may exhibit one or more of the following four hazardous characteristics: ignitability, reactivity, corrosivity or toxicity. The rule does not apply to sharps, infectious or biohazardous waste and most medical or contaminated materials.

If an organization opts to manage waste under the UWR, it could move from being a "generator" to a "handler." From the EPA's standpoint, the benefits of moving to UWR are that it will reduce the regulatory burden on organizations, reduce the need to classify and apply special handling for RCRA waste, standardize the accumulation time limits to one year, reduce recordkeeping and training, and facilitate "take-back" programs.

The downside risk is that there will be less life cycle control over hazardous materials and, depending on the state authorization under which an organization operates, the rule may have no consequence because it is superseded by more stringent state regulations. Further, the rule does not address all point-of-care materials, so the waste generator is left with establishing two training procedures—one for UWR and another for those materials that still fall under RCRA.

A second, but less likely, scenario would have the EPA add a number of currently non-RCRA pharmaceuticals to the UWR list, along with the RCRA pharmaceuticals. This would have the effect of significantly increasing the number of materials that require UWR handling. It would benefit the environment and probably be cost neutral for waste handlers, but it could still be confusing or superseded if the state regulations are more demanding.

For more on the EPA proposal, environmental services professionals should consult *Federal Register* Vol. 73, No. 232, Dec. 2, 2008/Proposed Rules (pages 73520 to 73544), which can be accessed on the Internet at **www.epa.gov/fedrgstr/EPA-WASTE/2008/December/Day-02/f28161.pdf**. Additionally, queries about the regulations can be directed to the "Frequent Questions" link on the EPA's Web site at **www.epa.gov/epawaste/hazard/wastetypes/universal/pharm.htm**.

DEA seeks consistency

The DEA's proposed rule for "Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration" [Docket No. DEA-316A] seeks options for the safe and responsible disposal of dispensed controlled substances from individual patients (ultimate users) in a manner consistent with the Controlled Substances Act (CSA) and its implementing regulations.

The DEA defines controlled substances as "those substances listed in the schedules of the CSA and 21 CFR 1308.11-1308.15, and generally include narcotics, stimulants, depressants and hallucinogens that have a potential for abuse and physical and psychological dependence, as well as anabolic steroids."

With regulations in a state of flux, it is important to monitor developments at the two federal agencies and the states.

Under the current closed system, strict recordkeeping is required and controlled substances may only be transferred between DEA registrants or exempted persons or entities until they are dispensed to the ultimate user. This means that once a controlled substance is "dispensed to the ultimate user," DEA registrants cannot take back controlled substances from ultimate users. This includes "reverse distributors" that routinely accept controlled substances for disposal from other DEA registrants.

Controlled substances can only be returned to a DEA registrant by an ultimate user after receiving permission from a local DEA Special Agent in Charge—an onerous and seldom-used option. The only exception is when the DEA grants temporary allowances—for community hazmat collection days, for instance—to law enforcement agencies to receive controlled substances from ultimate users.

In practice, any controlled substance dispensed to the public by a pharmacist or other health care practitioner, including veterinarians, cannot be recovered and must be disposed of by the individual. Consequently, the substances are discarded in regular household trash, through the wastewater system or diverted for other nonprescribed, often nonlegitimate uses.

Beyond the public, the disposal issue impacts non-DEA registrant health organizations. It is especially onerous for long-term care facilities and nursing homes, where rapidly changing prescriptions due to patient developments or death—or mishandled drugs during dispensing—can result in non-DEA registrant surpluses that require disposal.

The DEA recognizes that, beyond the environmental effects of the current system and the opportunity for diversion, there is also a financial cost in that dispensed but unconsumed substances could be redirected to other legitimate uses. Several states encourage reuse of pharmaceuticals, but this option cannot be implemented under current rules.

DEA Docket No. DEA-316A sought comments from ultimate users, state and local law enforcement agencies and publicly owned treatment facilities, concerned interest groups, long-term care facilities, hospices and in-home care groups, pharmacies, narcotic treatment programs, reverse distributors, state regulatory agencies and all interested parties on "how [the] various entities would address the issue of the disposal of dispensed controlled substances held by DEA nonregistrants in light of the current restrictions that are in place."

For more on the DEA's proposed rule, environmental services professionals should look at *Federal Register* Vol. 74, No. 12, Jan. 21, 2009/Proposed Rules (pages 3480 to 3487), which can be accessed at **http://edocket.access.gpo.gov/2009/pdf/E9-1056.pdf**.

Changes on the state level

At the state level, regulators for the most part are awaiting the outcome of the EPA and DEA processes. However, there are a few exceptions. Michigan and Florida have already reclassified pharmaceuticals that designate as RCRA hazardous waste into the UWR category in advance of the adoption of the new rules. The EPA has

allowed this anticipatory rule-making.

In April 2008, Washington state published an "Interim Enforcement Policy: Pharmaceutical Waste in Healthcare" notice that provides an option to the existing rules for managing pharmaceutical waste. (See **www.ecy.wa.gov/pubs/0704024.pdf**). Non-RCRA (state regulated) pharmaceutical waste may be disposed of at a municipal incinerator, permitted medical waste incinerator or RCRA-permitted incinerator. Pharmaceutical waste with RCRA codes must be handled as RCRA waste. There continues to be active debate at the state level as other states consider implementing additional pharmaceutical regulations.

Monitoring developments

With regulations in a state of flux, it is important to monitor developments at the two federal agencies and the states. The comment periods have closed for both the EPA and DEA, so the final rules can be expected later in 2009 or in 2010.

Yet, once published, states have the ability to implement more stringent rules than the federal regulations. The rules must be ratified by the individual states before they are enacted. About a quarter of the states will instantly ratify the changes but the majority will review them before they are enforced adding uncertainty to both the final outcome and the timeline. Moreover, since the review and ratification timelines vary or are not defined, impacted institutions cannot know when they will be required to implement the changes.

Other states, such as California, currently have more stringent rules. They could continue to enforce higher standards than the federal rules, which will cause permanent differences in how materials are handled within their jurisdictions.

The bottom line is that it is incumbent upon waste material generators such as hospitals to keep up with regulations from all federal and state agencies in order to understand the timing and ramifications for pharmaceutical waste management. This is the only way to adequately anticipate and prepare to implement the changes. **HFM**

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