No Flushing Allowed:
EPA Issues Guidance on Disposal of Unused Pharmaceuticals

The Environmental Protection Agency (EPA) recently issued a draft guidance document describing methods for healthcare facilities (such as hospitals, long-term care facilities, medical clinics and doctors’ offices) to legally manage and dispose of unused pharmaceuticals and avoid violating federal or state laws. This action reflects the EPA’s heightened concern regarding pharmaceuticals detected in surface waters and drinking waters. The disposal of pharmaceutical waste is regulated under the Federal Resource Conservation and Recovery Act (RCRA). As a first step, EPA is focusing on large institutions — those most likely handling substantial quantities of unused pharmaceuticals.

Pharmaceutical chemicals have been found in increasingly elevated concentrations in our nation’s rivers, lakes, streams and drinking water.
studied pharmaceutical disposal practices at healthcare facilities and believes that the practice of disposing large quantities of unused pharmaceuticals down the drain is a direct cause of the increasing amount of pharmaceutical chemicals making their way to and contaminating our nation’s waters. Based on this study, EPA recently circulated the Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities (Pharmaceuticals BMP).

The Pharmaceuticals BMP provides hospitals, medical clinics, doctors’ offices, long-term care facilities, veterinary facilities and medical professionals a means to evaluate their pharmaceutical disposal practices. More importantly, it provides two methods to manage unused pharmaceuticals:

1. Reduce pharmaceutical waste
2. Identify, manage and dispose of pharmaceutical waste in compliance with federal and state laws.

Reducing Pharmaceutical Waste. EPA recognizes that implementing effective inventory controls through the use of timely purchasing and tracking methods is the simplest and least expensive method to avoid generating pharmaceutical waste. Additionally, transferring unused pharmaceuticals to private companies legally authorized or registered to receive unused pharmaceuticals is another method that EPA and the federal government intend to implement to reduce unused pharmaceuticals from becoming pharmaceutical waste requiring disposal.

Identifying, Managing and Disposal of Pharmaceutical Waste. Pharmaceutical waste is typically generated at a large number of points in relatively small quantities across a medical facility, such as nursing stations, pharmacies and patient, emergency and operating rooms. EPA understands that many medical facilities are unaware that RCRA hazardous waste regulations apply to their pharmaceutical waste, requiring the facility, as “generator,” to identify or “characterize and properly dispose of” the pharmaceutical waste as hazardous or nonhazardous. Nonetheless, medical facilities must comply with the RCRA requirements since handling and storage requirements differ greatly depending on the characterization as hazardous or nonhazardous. Once a medical facility “knows thy waste,” it is able to do the following:

a) Separate the hazardous pharmaceutical waste from the nonhazardous
b) Determine how to manage the waste
c) Determine whether any permits are required and whether any storage time limits apply
d) Properly and timely dispose of the pharmaceutical waste
As explained in the Pharmaceuticals BMP, medical and healthcare facilities are subject to federal and state requirements for managing unused pharmaceuticals. Federal laws and programs that regulate the management and disposal of unused pharmaceuticals include the following:

a) Controlled Substances Act that is administered by the Drug Enforcement Agency
b) RCRA
c) Centers for Medicare and Medicaid Services
d) Health Insurance Portability and Accountability Act

State laws may implement these federal laws or programs, and may be broader and more stringent than the federal requirements.

What You Should Do Now

Health care facilities should evaluate EPA's proposed guidance as soon as possible, submit any comments to EPA by November 8, 2010, and prepare to evaluate their unused pharmaceutical management practices in light of EPA's proposed guidance to assess and make any changes that might be appropriate to assure compliance with federal and state requirements.

More details about the Pharmaceuticals BMP can be found online at http://water.epa.gov/scitech/wastetech/guide/unusedpharms_index.cfm. Public comments on the Pharmaceuticals BMP may be submitted to unusedpharms@epa.gov until November 8, 2010.

For More Information

Should you require further information on this subject or any matters involving Environmental and Natural Resources law, please contact Luke Narducci at 602.650.2301 or lnarducci@polsinelli.com.
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