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HEALTHCARE FACILITIES FACE NEW RULES FOR DISPOSING OF PHARMACEUTICALS

On August 31, 2015, the US Environmental Protection Agency (EPA) Administrator signed the proposed Management Standards for Hazardous Waste Pharmaceuticals rule outlining management and disposal standards for hazardous waste pharmaceuticals that are generated specifically by healthcare facilities.

Additionally, this rule "clarif[ies] the regulation of the reverse distribution mechanism used by healthcare facilities for the management of unused and/or expired pharmaceuticals" and aims to "strengthen environmental protection" by prohibiting the flushing of hazardous wastes down the toilet or drain. According to an EPA press release, this regulation will "prevent the flushing of more than 6,400 tons of hazardous waste pharmaceuticals annually."

The Proposed Rule's Economic Impact

Although EPA contends that the cost impact of the rule will be trivial, the rule may have much larger dollar and operating impacts than EPA predicts, for three reasons:

1. There will be a ban on disposing of certain kinds of pharmaceuticals down the sewer or sending them to a landfill. As a practical matter, this may be most easily implemented by banning all sewer (flushing) or landfill disposal of any waste pharmaceuticals, a rule some states and cities are already adopting to improve the discharges from sewage treatment plants.
2. Certain medical devices (e.g., IV bags, tubing) used to administer some pharmaceuticals, and contaminated with them, will also have to be handled as hazardous waste. If a healthcare facility adopts a general rule banning sewer and landfill disposal of all pharmaceuticals, the volume of contaminated used medical equipment requiring treatment as hazardous waste will also increase.
3. Operating costs will increase, and these costs probably have not been considered yet in negotiating reimbursement rates with insurers and by the federal agencies that determine reimbursement rates under federal programs.

A detailed review of the rule focusing only on direct costs is likely to miss these very important impacts. In deciding whether to comment, and in preparing to comply, we strongly recommend that healthcare facilities and health insurers quickly and carefully determine what the increased costs of a sewer and landfill ban on pharmaceuticals will be, and whether these costs are recoverable under current contracts and rules.

Background

This proposed rule is the EPA's response to commenters' concerns regarding its 2014 Notice of Data Availability, 73 Fed. Reg. 8,926 (Feb. 14, 2014), for the retail sector and its 2008 proposed Universal Waste rule, 73 Fed. Reg. 73,520 (proposed Dec. 2, 2008), which was never finalized, and addresses stakeholders' concerns regarding difficulties implementing the Resource Conservation and Recovery Act (RCRA) Subtitle C hazardous waste regulations for hazardous waste pharmaceuticals generated at healthcare facilities.

Under the proposed rule, "healthcare facilities" is defined broadly and includes:

> any person that (1) provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) sells or dispenses over-the-counter or prescription pharmaceuticals. This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and hospitals.

The Proposed Rule's Impact on Healthcare Facilities

Under this proposal, hazardous wastes from long-term care facilities will no longer be exempt from regulation as household hazardous waste under the RCRA unless (1) the hazardous waste pharmaceuticals are controlled substances and two combustion and disposal conditions are satisfied, or (2) the hazardous waste generated by the facility is a small enough quantity to qualify for reduced regulatory requirements. Therefore, unless either exception is applicable, hazardous waste generated at a long-term care facility will be subject to both the RCRA Subtitle C management and proposed standards.

Implementation of the proposed rule will affect the operations of healthcare facilities. Common practices of disposing unused or expired drugs through drains or household-type waste would cease, as the new rule would ban healthcare facilities and reverse distributors from discharging hazardous waste pharmaceuticals to sewer systems. Entities that transport and dispose of regulated waste pharmaceuticals will also be required to comply with record-keeping requirements. Additionally, the method and location of disposal will be determined and mandated depending on the substance being disposed. Healthcare facilities will also be required to comply with labeling of hazardous waste and emergency planning and preparedness with the intent of enhancing the safety of the facility, employees and the general public.

The Proposed Rule's Impact on State and Other Federal Laws and Regulations

The EPA has taken the position that its proposed rule is "more stringent than the current federal standards." Accordingly, implementation of the proposed rule may require that states modify their programs to ensure compliance with the new federal standard. For example, EPA's historical position on reverse distribution asserted that pharmaceutical products returned for credit did not become waste until a determination is made to discard them. Most states embrace this historic position. For example, in a December 2014 guidance document, the New York State Department of Environmental Conservation indicated that "[m]aterials shipped to a reverse distributor are considered products and not wastes until they are processed by the reverse distributor." However, the proposed rule reinterprets this position and provides that the decision to send a pharmaceutical to a reverse distributor is the point at which a decision is made to discard the substance.

If the proposed rule is implemented, states may be required to modify their standards to adopt the new rule. The EPA can authorize an individual state hazardous waste program to operate in lieu of the federal program, but the authorized state's program must be "at least as stringent as, and consistent with, the federal program." Thus, if a state's program is less stringent than the proposed EPA rule, the state must comply with federal requirements.

The EPA has made an effort not to create overlap in regulation with the Drug Enforcement Agency by providing in the proposed rule a conditional exemption from RCRA regulation for pharmaceuticals that are regulated as controlled substances. The exemption is conditioned on the waste being collected, stored, transported, destroyed and disposed in compliance with all DEA requirements for controlled substances.

The proposed rule was published in the Federal Register on September 25, 2015. The EPA currently is soliciting comments for recommendations and changes or amendments from the public. Comments must be received by the EPA no later than 5 p.m. on November 24, 2015, and may be submitted electronically, by postal mail or by hand delivery.

Our lawyers are experienced in providing expert legal advice to our clients regarding all aspects of dealing with hazardous waste storage and disposal, as well as other environmental matters. If you would like additional information about the proposed rule or are interested in submitting a comment, please contact us.

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