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EPA Announces Plans to Develop New Regulations to Address Healthcare Facilities' Generation and Disposal of Hazardous Waste Pharmaceuticals

The United States Environmental Protection Agency (EPA) has announced that it will develop a new rule to address the management and disposal of hazardous waste pharmaceuticals generated by healthcare facilities. The EPA has yet to release details about this rulemaking; however, the EPA has confirmed that it will only apply to pharmaceutical waste that meets the hazardous waste definition in the Resource Conservation and Recovery Act (RCRA) and anticipates publishing the proposed rule for public comment in August 2013. This announcement means that the EPA will not finalize its 2008 proposed rule to add hazardous pharmaceutical wastes to the universal waste program.

The EPA currently regulates healthcare facilities' (including pharmacies) disposal of hazardous pharmaceutical waste under RCRA's hazardous waste generator regulations. However, these regulations are particularly unsuited for healthcare facilities as they generate hundreds of different types of pharmaceutical waste in numerous locations of which only a very small portion constitutes hazardous waste under RCRA. As such, sorting out the hazardous waste from the non-hazardous waste can be quite burdensome and many healthcare facilities have had difficulty maintaining compliance with RCRA.

In 2008, the EPA proposed to amend the universal waste regulations to include hazardous pharmaceutical waste in order to relieve some of the burden imposed on healthcare facilities under RCRA and to encourage hospitals to treat all pharmaceutical waste, hazardous or not, as universal waste. However, the EPA recently decided to abandon this proposed rule, citing concerns related to the reduced notification and tracking requirements under the universal waste regulations.

Meantime, in the absence of a final federal rule, states have enacted their own regulations to alleviate some of this burden on health care facilities. For example, Florida has implemented regulations that treat hazardous pharmaceutical waste as universal waste pursuant to its delegated authority under RCRA. Similarly, California recently amended the state's Medical Waste Management Act to make it easier for health care facilities to avoid RCRA regulations by increasing their ability to utilize reverse distributors for disposal. However, it is uncertain how the EPA's proposed new rule may impact these state regulations.

The information contained herein is based on a summary of legal principles. It is not to be construed as legal advice. Individuals should consult with legal counsel before taking any action based on these principles to ensure their applicability in a given situation.

Regardless, many states, including Wisconsin, have yet to promulgate any regulations that differ from the EPA's RCRA regulations for the handling and disposal of pharmaceutical waste. As such, until the EPA finalizes a new rule, many healthcare facilities are still required to comply with RCRA generator regulations when disposing of hazardous pharmaceutical waste and may be subject to federal or state enforcement if they fail to comply.

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