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Office of Inspector General's Identification of 100s of Pharmaceuticals that EPA Should be Regulating as Hazardous Waste may be a Harbinger for Regulatory Action

A recent report by the Office of Inspector General has identified significant deficiencies in U.S. Environmental Protection Agency's (EPA) regulation of pharmaceuticals that are hazardous wastes when discarded. In its response to these findings, the EPA indicated that it expects to propose new regulations for hazardous waste pharmaceuticals in 2013. The EPA also concluded that there may be widespread noncompliance in the health care industry with current hazardous waste regulations. Health care facilities may consider reviewing their current management of pharmaceutical waste in light of current laws and the potential impact of an expanded list of hazardous waste pharmaceuticals that may soon be expected.

On May 25, 2012, the Office of Inspector General published a review of regulation of hazardous waste pharmaceuticals (HWP). The review found that since 1980, EPA has not updated its list of pharmaceuticals that are considered as hazardous waste when discarded. Nor has EPA established a process for updating the list of HWPs. As a consequence, the Inspector General found potentially hundreds of pharmaceuticals that are not listed but may be HWPs, 11 of which could meet the criteria for acute hazardous waste that has a lower threshold for regulation. In its response to these findings, EPA indicated that in Spring 2013 it expects to propose new regulations governing the handling and disposal of pharmaceutical waste. There may be steps health care facilities should consider to prepare for potential changes in HWP regulations.

Disposal of HWPs is regulated under the Resource Conservation and Recovery Act (RCRA). Under RCRA, EPA identified 31 pharmaceuticals as HWPs whereas the National Institute for Occupational Safety and Health and the Occupational Safety and Health Administration have identified over 100 drugs as hazardous pharmaceuticals. EPA regulates listed pharmaceuticals as hazardous waste (H-Listed) or acutely hazardous waste (P-Listed). The regulatory thresholds for acute hazardous waste is considerably lower than for H-listed wastes. For example, facilities generating more than 2.2 pounds of P-Listed waste in any single month are considered as Large Quantity Generators, whereas the equivalent threshold for H-Listed waste is 2,200 pounds per month.

In addition to identifying EPA's inaction in identifying HWPs, the Inspector General also found that EPA has concluded that there may be widespread noncompliance in the health care industry with current hazardous waste regulations. For example, a 2004 increase in enforcement activities in EPA Regions 1 and 2 related to HWPs led to fines ranging from $40,000 to $250,000 for multiple facilities not complying with RCRA regulations.

In response to the Inspector General's report, EPA indicated that it agreed that waste pharmaceuticals is an area in need of attention and expects to propose new rules in Spring 2013. EPA also indicated its intent to address the perceived extensive noncompliance with increased outreach and compliance to assist the health care industry for the current regulations.

Clearly, the Inspector General's review indicates a potential for increased regulatory scrutiny on the way health care organizations manage pharmaceutical waste. Health care facilities may consider reviewing their current management of pharmaceutical waste in light of current laws and the potential impact of an expanded list of HWPs that may soon be expected.

Please contact Art Harrington, Duncan Moss or any other Environment & Energy Strategies team member should you have questions concerning hazardous waste rules for health care facilities.

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