At a Glance

Why We Did This Review

We conducted this review to evaluate the U.S. **Environmental Protection** Agency's (EPA's) process to identify and appropriately classify pharmaceuticals as hazardous waste and to ensure their safe disposal.

Background

The discovery of a variety of pharmaceuticals in water has raised concerns about potentially adverse environmental consequences of these contaminants. Studies have suggested the detection of pharmaceutical compounds in treated wastewater effluent, streams, lakes, seawater, drinking water, and groundwater, as well as in sediments and fish tissue. EPA has the authority under the Resource Conservation and Recovery Act (RCRA) to regulate hazardous waste pharmaceuticals (HWPs) to ensure safe management and disposal practices.

For further information, contact our Office of Congressional and Public Affairs at (202) 566-2391.

The full report is at: www.epa.gov/oig/reports/2012/ 20120525-12-P-0508.pdf

EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal

What We Found

Since 1980, EPA has not used its RCRA authority to determine whether pharmaceuticals may qualify as hazardous waste. EPA also has not established a process for the regular identification and review of pharmaceuticals that may qualify for regulation as hazardous waste. Without a regular process, EPA cannot provide assurance that pharmaceuticals that may pose a hazardous risk to human health and the environment have been identified. We identified eight chemicals found in pharmaceuticals that meet EPA's criteria for regulation as acute hazardous waste, but wastes containing these chemicals are not regulated as such. There are over 100 drugs that federal occupational safety organizations have identified as hazardous but may not have been reviewed by EPA to determine whether they may qualify as hazardous waste. EPA staff stated they have started examining these drugs for listing as hazardous waste. Further, the state of Minnesota recently noted that there has been a proliferation of pharmaceutical development since RCRA regulations were established. Our review has identified a risk that there are unknown but potentially dangerous unregulated HWPs that may be unsafely disposed and released into the environment.

An additional challenge to ensuring the safe disposal of HWPs is that some health care facilities, such as hospitals, may be unaware of federal hazardous waste regulations. The state of Minnesota, for example, has reported that there is a "general lack of awareness by the health care industry of RCRA regulatory requirements." This may result in mismanagement of hazardous waste pharmaceuticals.

In 2008, EPA proposed an amendment to the Universal Waste Rule to address pharmaceutical wastes. However, no action on the Rule has occurred since the close of the public comments period in 2009. During our review, EPA staff informed us that the Agency has decided to develop another proposal for the regulation of hazardous waste pharmaceuticals at health care facilities. EPA staff stated that "due to substantial negative public comments received on the 2008 universal waste proposal, the Agency is developing a revised proposal for regulation of hazardous waste pharmaceuticals at healthcare facilities." EPA anticipates the proposal will be available for public comment in spring 2013.

What We Recommend

We recommend that EPA establish a process to review pharmaceuticals for regulation as hazardous waste and develop an outreach and compliance assistance plan for health care facilities managing HWPs.