EPA Issues Proposed Hazardous Pharmaceutical Waste Management Rule

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On August 31, 2015, EPA proposed a rule pursuant to the Resource Conservation and Recovery Act (RCRA) to create new management standards for discarded pharmaceuticals which are regulated as hazardous wastes. The rule will apply to pharmacies, hospitals, doctors' offices and other health care facilities as well as reverse distributors and treatment, storage and disposal facilities that handle hazardous pharmaceuticals.

EPA declined to manage hazardous waste pharmaceuticals under RCRA's Universal Waste Rule as originally proposed in 2008 and as Michigan and Florida currently regulate such wastes. The Universal Waste program offers management standards for certain "low risk" hazardous wastes with less stringent requirements than RCRA's Subtitle C requirements for generators of other hazardous wastes. Citing the need to track hazardous pharmaceuticals, EPA is instead proposing to create a new RCRA Subpart P that would apply to generators and disposers of discarded hazardous pharmaceuticals. Michigan and Florida are the only two states that currently regulate pharmaceuticals as Universal Wastes. Both states will be required to modify its RCRA program to replace its rules with the more stringent federal requirements. Fortunately, the proposed standards are very similar, with a few exceptions, to Michigan's Universal Waste requirements and should not, if promulgated, require any significant changes to how Michigan Healthcare Facilities currently handle their hazardous pharmaceuticals. EPA will take comments on the proposed rule for 60 days from the date it is published in the Federal Register. Michigan Healthcare Facilities should note several unique provisions of the proposed rule

- Disposing of hazardous pharmaceuticals by flushing down a toilet or pouring in a drain is strictly prohibited. Hazardous waste pharmaceuticals must be disposed of at a permitted

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RCRA disposal facility.

- The rule applies to "pharmaceuticals" which meet the RCRA definition of hazardous wastes. "Pharmaceuticals" is broadly defined to include not only items recognized by the U.S. Food and Drug Administration (FDA) as drugs (both those that require a prescription and those available 'over the counter) but other items such as dietary supplements and drugs with radioactive components. In addition, pharmaceutical residues in containers, personal protective equipment contaminated with hazardous pharmaceuticals and clean-up materials from spills of hazardous pharmaceuticals are considered regulated hazardous wastes. EPA has however, proposed to exempt hazardous pharmaceuticals which are regulated as controlled substances as long as they are incinerated and managed in accordance with U.S. Drug Enforcement Agency regulations Used sharps and needles handled in accordance with state and federal medical waste laws are not included in the definition.
- The rule distinguishes between "potentially creditable" and "non-creditable" pharmaceuticals, with a majority of the Part P management standards applying only to non-creditable hazardous waste pharmaceuticals. A "non-creditable hazardous waste pharmaceutical" is a hazardous waste pharmaceutical that is not expected to be eligible for a manufacturer's credit. Conversely, a "potentially creditable hazardous waste pharmaceutical" is one that has the potential to receive a manufacturer's credit and is 1) unused or un-administered; and 2) unexpired or less than one year past expiration date.
- Hazardous waste manifests must be used for shipment of non-creditable hazardous pharmaceuticals; however, generators need not assign or identify hazardous waste codes but must simply identify the materials as "Hazardous Waste Pharmaceuticals". Copies of signed manifests must be kept for three years.
- Healthcare Facilities that send potentially creditable hazardous pharmaceuticals to reverse distributors do not have to manifest such shipments. In addition, there are no specific management standards for potentially creditable hazardous pharmaceuticals or accumulation limits at the generating Healthcare Facility. Reversing prior interpretations, EPA is now proposing that "potentially creditable pharmaceuticals" are not "products" and once a decision is made to send them to a reverse distributer, they are "discarded" and are considered wastes. As such, reverse distributors and treatment, storage and disposal facilities handling hazardous pharmaceuticals will have to comply with new Part P management standards.

Those in the health care industry who had advocated for inclusion of pharmaceutical wastes in the Universal Waste Program to provide relief from oftentimes confusing and onerous RCRA hazardous waste regulations may be disappointed. However, this new proposal, while imposing some additional requirements beyond those in the Universal Waste Program, nevertheless, provides much of the relief and certainty the industry has demanded. For additional information or inquiries regarding our services related to EPA's proposed hazardous pharmaceutical rule contact either:

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