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What Does the Health Care Industry Do Now When Disposing "Hazardous Waste" Pharmaceuticals?

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POTENTIALLY AFFECTED HEALTH CARE FACILITIES SHOULD EVALUATE CURRENT MANAGEMENT PRACTICES, EVALUATE BEST MANAGEMENT PRACTICES FOR REGULATED FACILITIES, AND DEVELOP A PLAN TO PREPARE FOR AND MANAGE A REGULATORY INSPECTION.

The Environmental Protection Agency (EPA) estimates that 174,023 health care facilities nationwide may be directly affected by its Management Standards for Hazardous Waste Pharmaceuticals rule[1] (available at https://www.gpo.gov/fdsys/pkg/FR-2015-09-25/pdf/2015-23167.pdf), which was proposed in September 2015. In response, many of these health care facilities and their trade associations filed comments with EPA in late December 2015. Now, these facilities must wait while EPA digests the comments and

attempts to address concerns by either modifying the rule or explaining the reasons why it did not accept the comments. The following summarizes the major components of the proposed rule and provides an overview of the major comments submitted to EPA. It also provides some insight on what, if anything, can be done now by parties that would be affected by the proposed rule.

The Definition of "Pharmaceutical" Was Broadened

EPA's proposed rule includes a very broad and, in some respects, vague definition of "pharmaceuticals."[2] For example, the expanded definition includes supplements (even though the Food and Drug Administration does not regulate supplements as pharmaceuticals) and items containing pharmaceutical residuals. With such a broad definition, the number of parties subject to regulation may significantly increase. A wide variety of commenters objected to the breadth of this definition, specifically as it applied, or could be misinterpreted to apply, to their segment of the health care industry.

EPA Considers Pharmaceuticals Returned to Manufacturers Through Reverse Distributors as "Discarded"

EPA's proposed rule would regulate pharmaceuticals that are being returned to manufacturers through reverse distributors because these pharmaceuticals are allegedly being "discarded." This appears to be the latest effort by EPA's Office of Resource and Recovery to extend dramatically the scope of the hazardous waste disposal laws by contorting the meaning of the word "discard."

Reverse distributors, pharmaceutical manufacturers, pharmacies and drug stores argued vigorously that pharmaceuticals in the reverse distribution system are not "discarded" within the meaning of the Resource Conservation and Recovery Act (RCRA) because they have monetary value (*i.e.*, the credit being provided to the returned items) and they are still subject to recall. They further assert that (a) EPA's expanded interpretation of "discard" is inconsistent with prior EPA interpretations, (b) there is no evidence in the record of environmental damage from pharmaceuticals being returned to manufacturers, and (c) EPA has significantly underestimated the regulatory burden of such a change.

EPA Proposes to Ban Discharges of Pharmaceuticals into Publicly Owned Treatment Works

EPA proposed a ban on the discharge of pharmaceuticals into sewer plants. Some commenters (particularly municipalities and state regulators) expressed support for reducing the discharge of hazardous waste pharmaceuticals (and, in some cases, any pharmaceuticals) into sewers because these plants were not designed to treat

pharmaceuticals and pharmaceuticals have been found in drinking water downstream of sewer plants. However, other commenters objected to this ban as being legally flawed, unjustified by commensurate benefits and impractical, noting the following:

- the Clean Water Act pretreatment program governs such discharges, not the RCRA
- the benefits calculation assumes that no treatment now occurs
- the proposed rule provides no details on practical implication issues (such as where there is a *de minimis* level, who enforces the ban and who pays for the inspection of 170,000 or more newly regulated sources)
- existing measured levels of pharmaceuticals are several orders of magnitude lower than the average level assumed by EPA's benefits calculation
- the administrative record does not document a significant risk from existing levels of pharmaceuticals in local waterbodies.

EPA's Proposed Rule Is Expansive, Covering a Diverse Universe of Health Care Facilities

The proposed rule covers not just hospitals and large reverse distributors, but includes a catchall category of "other" health care facilities. The other health care facilities category is extraordinarily diverse and broad (*e.g.*, pharmacies, veterinary clinics, physicians' offices, dental offices, other health practitioners, outpatient care centers, other ambulatory health care services, nursing care facilities, continuing care retirement communities, and medical examiners). Many representatives from these categories noted that the "other health care" category contains facilities that vary in the type of pharmaceuticals involved, the size of the office, the degree of experience with pharmaceuticals and the resources available. They also noted that the nature of the entities within this category are very different from hospitals and reverse distributors. The comments explain these differences and note that many of the record-keeping and other requirements will be onerous to such small entities.

The Proposed Rule States that Landfilling Pharmaceuticals Is Harmful to the Environment

The proposed rule argues that landfilling of even nonhazardous pharmaceuticals is harmful to the environment and recommends incineration for disposal of pharmaceuticals. The National Association of Clean Water Agencies and several municipalities and state agencies supported these statements. However, several commenters point out that there is no evidence in the administrative record supporting this assertion of harm.

What Do Potentially Regulated Entities Do Now

The dilemma facing potentially regulated entities is what to do prior to the issuance of a final rule. The Office of Management and Budget's schedule for issuing a final rule is September 2016. Given the volume of comments, this date is optimistic. The rule is far-reaching, and the nature of the regulated entities and their issues vary. Significant modifications to the proposed rule before final adoption are certain. If a final rule is not issued prior to the November 8, 2016 presidential election, the final rule may be delayed until a new administration can review the policy issues.

However, a delay in the issuance of a final rule is not necessarily helpful. Prior to the promulgation of the 2015 proposed rule, enforcement actions had increased against health care facilities, big box chain stores that sell pharmaceuticals and hospitals, among others. EPA states in the preamble to the proposed rule that the existing regulations already apply to health care facilities and that most of the affected health care facilities are currently in violation (in fact, this assertion is repeated **nine times** in the preamble). If this allegation is true, it may lead EPA regional offices, states and local governments to increase enforcement of the existing regulations. Health care facilities may face increased inspections and the need to defend against enforcement actions.

It may be in the best interest of potentially affected health care facilities (particularly those with sustainability policies) to evaluate current management practices, including the performance of a compliance audit; evaluate best management practices for regulated facilities; and develop a plan to prepare for and manage a regulatory inspection. Regulated parties may want to consider including in any audit an evaluation of compliance with existing regulations, as well as a comparison of existing practices with elements of the proposed Management Standards for Hazardous Waste Pharmaceuticals rule. Although this is not an existing regulation and would not necessarily trigger corrective action, by assessing various elements of the proposed rule, particularly those that will likely be included in the final rule, the regulated parties may be able to better plan for taking future corrective action (*e.g.*, begin budgeting) or proactively take corrective

action where there are not significant cost implications (*e.g.*, minor facility adjustments/ modifications, handling/management procedures, training and record keeping). This may reduce the future regulatory burden of the final rule and reduce the likelihood of a significant enforcement action that may result from an inspection that occurs pre- or post-final rule.

Endnotes

1. 80 Fed. Reg. 58,014 (proposed Sept. 25, 2015). The number of health care facilities is based on the extremely broad definition of the EPA, as discussed in this Client Alert.

2. Pharmaceutical means "any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act, prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals." 80 Fed. Reg. at 58,084.