American Veterinary Distributors Association (AVDA)
Health Industries Distribution Association (HIDA)
Healthcare Distribution Management Association (HDMA)
National Coalition of Pharmaceutical Distributors (NCPD)

December 17, 2015

BY ELECTRONIC FILING
http://www.regulations.gov
Docket No. EPA-HQ-RCRA-2007-0932

Kristin Fitzgerald
Environmental Protection Agency
Office of Resource Conservation and Recovery (5304P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: EPA-HQ-RCRA-2007-0932 (Management Standards for Hazardous Waste Pharmaceuticals)

We, the undersigned associations, would like to take this opportunity to provide our comments to the Environmental Protection Agency ("EPA") on the Proposed Rule EPA-HQ-RCRA-2007-0932, "*Management Standards for Hazardous Waste Pharmaceuticals*" (the "proposed rule," "rule," or "proposal").[1]

Our collective organizations represent pharmaceutical wholesale distributors, veterinary product wholesale distributors, and medical device wholesale distributors of products covered by the proposed rule. A description of our respective organizations is included below. As such, we have a number of concerns and recommendations in common, despite the variation in our members' business models and product mix. We wish to highlight our shared concerns with the proposal and provide recommendations we have agreed upon along with our justifications for them.

Overview

We collectively support EPA's sector-based proposal to create a separate, new Subpart P – Hazardous Waste Pharmaceuticals – of 40 C.F.R. Part 266 to address the unique issues of disposal of hazardous waste pharmaceuticals. We also understand the underlying reasons for

[1] 80 Fed. Reg. 58,014 (September 25, 2015)

EPA's efforts to eliminate sewering and to direct hazardous pharmaceutical waste into secure, environmentally sound methods for disposal.

As noted, we agree with the reasons for creating this new Subpart for healthcare entities. However, those reasons are of equally, if not greater, applicability to wholesale distributors. Thus, we were frankly concerned and disappointed that the new Subpart P will not be applied to wholesale distributors.

Further, while the preamble states that EPA does not intend to apply the proposal to wholesale distributors, it is also possible, if not likely, that certain elements of the rule ***will*** apply, if it is finalized as proposed. This is because of the proposal to eliminate a critical interpretation, in effect for over 30 years, that pharmaceuticals sent to a reverse distributor for a determination that they are creditable under the manufacturer's returns policy are not waste until a determination has been made to discard them. Currently, the returns that our wholesale distributor members send to a reverse distributor are not considered wastes under the Resource Conservation and Recovery Act (RCRA). EPA is proposing a new requirement that, if applied broadly, deems a wholesale distributor's returns to reverse distributors to be waste that must be managed under Subpart C or Subpart D of EPA's RCRA regulations from the moment the wholesale distributor decides to send the product to the reverse distributor.

Unfortunately, many, if not most, reverse distributors are not licensed/permitted as either solid or hazardous waste disposal facilities. If the change is included in the final rule, we believe it could have the effect of barring wholesale distributors from shipping non-saleable, but creditable, products to the reverse distributor for a credit eligibility determination.

The combination of not applying Subpart P to wholesale distributors and elimination of the current credit determination policy has the potential for tremendous, and negative, impact on wholesale distributors' operations, efficiencies, and costs. Further, this impact would likely extend to both our members' suppliers and their healthcare facility customers.

Recommendations

Our organizations urge EPA to fully consider, and incorporate the following recommendations as the agency moves forward to a final rule:

- We request that EPA include wholesale distributors in the new Subpart P. EPA states that the new Subpart P for healthcare facilities will aid in their management of hazardous waste pharmaceuticals because it is difficult for healthcare facilities to predict the identity and quantity of wastes they will generate. This unpredictability is true for wholesale distributors as well.
- We also urge EPA to leave intact, and unchanged, the current policy that sending a product to a reverse distributor for credit eligibility determination is not an indicator of an "intent to discard".[2]

[2] 80 FR 58,043 Col 3. (September 25, 2015)

Discussion

A product becomes a waste – with the attendant requirements of RCRA – "if and when [it is] discarded or intended to be discarded." 40 C.F.R. § 261.33. We believe that EPA is incorrect in its conclusion that wholesale distributors "intend to discard" their products when they send them to reverse distributors for credit eligibility determination. Wholesale distributors do not "intend to discard" any product returned to a reverse distributor. A wholesale distributor sends a product to a reverse distributor in order to obtain a refund from the manufacturer and the reverse distributors determines whether the wholesale distributor's product is eligible for credit from the manufacturer. Only the manufacturer, or the reverse distributor, under precise guidance from the manufacturer, decides whether to discard the product.

Wholesale distributors do not wish to replicate the valuable business functions of reverse distributors who have the expertise, facilities, and management standards to efficiently and comprehensively make credit eligibility determinations for millions of products from thousands of wholesale distributors, healthcare facilities and other purchasers. Wholesale distributors are just as reliant on reverse distributors for this function as are healthcare facilities. Thus, we believe it is appropriate to apply the waste disposal requirements of the proposed Subpart P to wholesale distributors in an equivalent manner.

We believe the rule would have long-reaching and costly effects upon our members and the pharmaceutical supply chain:

- If wholesale distributors cannot send their returns to reverse distributors for credit eligibility determinations, they will have to manage these returns themselves. The resource demands upon wholesale distributors to undertake these processes would be significant. Wholesale distributors would have to add staff and substantially revise operational processes. Increased costs for wholesale distributors would likely result in increased costs to the entire supply chain, including healthcare facilities, providers, and their patients.

- Many of our members are small businesses who would likely be impacted disproportionately. The challenge of revising business processes would be incrementally greater for the smaller wholesale distributors who would have to meet the same requirements with fewer resources.

- EPA identifies no environmental benefits to eliminating the current credit policy and excluding wholesale distributors from Subpart P. In contrast, we believe there are many unexamined costs and, potentially, negative environmental impacts. Prior to the rule, wholesale distributors would have been able to send their products to a few reverse distributors who consolidated credit determination functions and coordinated with manufacturers to disposition product. If the rule were to be finalized as proposed, this activity would be spread over hundreds of distributor warehouses, creating a risk of generating more waste, while concurrently decreasing the efficient management of these products.

Conclusion

We would like to thank you for this opportunity to provide our comments on the Proposed Rule, which we hope are constructive in your understanding of hazardous waste pharmaceuticals and results in an equitable and reasonable approach to industry and to EPA.

Sincerely,

American Veterinary Distributors Association
Jackie King
Executive Director
443-640-1040x105
Jackie@kingmgmt.org

AVDA, a not-for-profit corporation, was established in 1976 as the national trade organization for businesses engaged in the distribution of animal health products. Our members distribute animal health supplies to some 60,000 veterinarians practicing in approximately 30,000 animal health clinics throughout the United States. AVDA distributor members distribute supplies exclusively to animal health entities and annual sales of these supplies are estimated at $5 billion. Those products include pharmaceuticals, biologicals, white goods, instruments and equipment, and pet foods. In addition, some AVDA member companies also serve the OTC market, made up of farm and feedlot operations, poultry producers, farm stores, etc. For more information about AVDA, visit www.avda.net.

Health Industries Distribution Association
Linda Rouse O'Neill
Vice President, Government Affairs
703.838.6125
rouse@hida.org

The Health Industry Distributors Association (HIDA) is the premier trade association representing medical-surgical products distribution. HIDA members deliver medical products and supplies, manage logistics, and offer customer services to more than 294,000 points of care including the nation's hospitals, nursing homes, labs and physician markets. Medical-surgical products distributors primarily distribute items used in every day medical services and procedures, ranging from gauze, gloves and syringes to diagnostic laboratory tests and capital equipment. For more information, visit www.HIDA.org.

Healthcare Distribution Management Association

Anita T. Ducca
Senior Vice President
703-885-0240
aducca@hdmanet.org

HDMA is the national association representing primary healthcare distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that 15 million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDMA and its members work daily to provide value and achieve cost savings, an estimated $42 billion each year to our nation's healthcare system. For more information, visit www.HealthcareDistribution.org.

National Coalition of Pharmaceutical Distributors

Karen L. Moody
President
National Coalition of Pharmaceutical Distributors
Phone: (305) 690-4233, Ext.234
Karen.Moody@atlanticbiologicals.com

The National Coalition of Pharmaceutical Distributors (NCPD) represents and promotes the specialty/independent pharmaceutical distribution sector before legislatures, regulatory agencies, industry stakeholders and the community at large. NCPD provides a collaborative venue for its members to exchange industry knowledge, ideas and best practices to enhance the value of the pharmaceutical supply chain and to ensure its safety.