Division of Environmental Response and Revitalization (DERR)
Hazardous Waste Management Program
May 6, 2019

Early Stakeholder Outreach — Hazardous Waste Pharmaceuticals and Airbag Modules and Airbag Inflators

Ohio EPA prepares early stakeholder outreach fact sheets to ensure stakeholders are brought into the review process as early as possible and to obtain additional input and discussion before development of interested party draft rules.

What do these rules cover?

The hazardous waste rules addressed by this Early Stakeholder Outreach (ESO) will be drafted to accommodate new federal rules regarding the management of hazardous waste pharmaceuticals, airbag modules, and airbag inflators. The hazardous waste rules are found in Ohio Administrative Code (OAC) Chapters 3745-50 to 3745-69, 3745-205, 3745-256, 3745-266, 3745-270, 3745-273, and 3745-279.

Why are these rules being sent out for Early Stakeholder Outreach?

The first step in the rule-making process is for Ohio EPA to identify that a rule needs to be amended, rescinded, or created. This ESO notification and request for information will allow for early feedback before the rule language has been developed by the Agency.

What changes are being considered and why?

The changes under consideration are federally-driven updates. Ohio's hazardous waste rules must match their federal Resource Conservation and Recovery Act (RCRA) counterpart regulations in 40 CFR Parts 260 to 279 if those federal regulations are more stringent than Ohio's current rules. Those federal rules that are less stringent are optional for Ohio to adopt; however, generally those optional rules provide regulatory flexibility or reduce the regulatory burden on the regulated community. A number of Ohio rules need to be rescinded, added, or amended to address changes to, or the creation of, their federal RCRA counterpart provisions, as published in the following Federal Registers (FRs):

How can I provide input?

The Agency is seeking stakeholder input on the concept of addressing these federal rulemakings in Ohio rules. When preparing your comments, be sure to:

- explain your views as clearly as possible;
- describe any assumptions used;
- provide any technical information and/or data used to support your views;
- explain how you arrived at your estimate for potential burdens, benefits or costs;
- provide specific examples to illustrate your views; and
- offer alternatives.

Written comments will be accepted through close of business **May 20, 2019**. Please submit input to:

DERR_rulecomments@epa.ohio.gov

What if I have questions?

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- Hazardous Waste Pharmaceuticals 84 FR 5816, dated Feb 22, 2019. Ohio rule citations have yet to be determined. Some of the provisions of these new or amended rules are optional for states to adopt, while others are required to adopt because they are more stringent than Ohio's current rules. U.S. EPA's final rule establishes cost-saving, streamlined standards for handling hazardous waste pharmaceuticlas to better fit the operations of the healthcare sector while maintaining protection of human health and the environment. Importantly, U.S. EPA's rule will make our drinking water safer and healthier by reducing the amount of hazardous waste pharmaceuticals entering our waterways by 1,644 to 2,300 tons on an annual basis by prohibiting all facilities subject to the rule from sewering them. This action will help address the issue highlighted by a growing body of publicly available studies documenting the presence of pharmaceuticals in drinking and surface waters as well as their negative impacts to aquatic and riparian ecosystems. In addition, under U.S. EPA's final rule, FDA-approved, over-the-counter nicotine replacement therapies (i.e., nicotine patches, gums and lozenges) will no longer be considered hazardous waste

when discarded, which will result in significant cost savings and burden reduction in the management of these types of nicotine wastes.

- Hazardous Waste Airbag Modules and Inflators 83 FR 61552, dated November 30, 2018. Ohio rule citations yet to be determined. The provisions of these new or amended rules are optional for states to adopt. Adoption of these rules is not required, but allows for regulatory flexibility. U.S.EPA's rule facilitates a more expedited removal of defective airbag inflators from vehicles by dealerships, salvage yards and other locations for safe and environmentally sound disposal by exempting the collection of airbag waste from hazardous waste reqirements as long as certain conditions are met.

Who will be regulated by these rules?

Anyone who is currently regulated by the hazardous waste management rules as a healthcare facility or reverse distributor managing hazardous waste pharmaceuticals, or anyone who manages airbag waste (*i.e.*, discarded airbag modules and airbag inflators) that is subject to hazardous waste regulations, is regulated by the rules in this ESO.

What is the rulemaking schedule?

At the close of the ESO comment period, the Agency will consider input provided by stakeholders and then draft the revised rules. The draft rules will be released for another comment period called Interested Party Review, which the Agency anticipates occurring in late summer 2019.

What input is the Agency seeking?

The following questions may help guide you as you develop your comments.

- Is the general regulatory framework proposed the most appropriate? Should the Agency consider any alternative framework?
- What options are available for improving an identified concept? What options are available for improving the existing rules?
- Are there considerations the Agency should take into account when updating the existing rules? Are there considerations the Agency should take into account when developing a specific concept?
- Is there any information or data the Agency should be aware of when developing program concepts or rule language?

The following questions may help guide you as you develop your comments. **Ohio EPA would especially like to hear information regarding the following from stakeholders who may be impacted by the amended and/or new program elements.**

- Would this regulatory program have a positive impact on your business? Please explain how.
- Would this regulatory program have an adverse impact on your business? If so, please identify the nature of the adverse impact (for example, license fees, fines, employer time for compliance).
- Ohio EPA would like your input on whether we should adopt the following optional provision: exemption of the P075 listing for nicotine gums, patches, and lozenges that are FDA-approved over the counter nicotine replacement therapies (premable section V). You can read about all the rule change at 84 FR 5816, dated 02/22/2019, in the preamble of the Management Standards for Hazardous waste Pharamceuticals federal rule.

Contact

For questions regarding this rule-making, contact Tammy Heffelfinger at (614) 644-2954 or Tammy.Heffelfinger@epa.ohio.gov.