

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 3745-266-504

Rule Type: New

Rule Title/Tagline: Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.

Agency Name: Ohio Environmental Protection Agency

Division: Division of Hazardous Waste

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I. Rule Summary

1. Is this a five year rule review? No
 - A. What is the rule's five year review date? Exempt
2. Is this rule the result of recent legislation? No
3. What statute is this rule being promulgated under? 119.03
4. What statute(s) grant rule writing authority? 3734.12
5. What statute(s) does the rule implement or amplify? 3734.12
6. What are the reasons for proposing the rule?

U.S. EPA promulgated the federal counterpart rule (40 CFR 266.504) and to remain consistent with the federal program, Ohio EPA needs to adopt the rule.

7. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.

This rule contains generator specific information for healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.

8. **Does the rule incorporate material by reference?** No
9. **If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.75, please explain the basis for the exemption and how an individual can find the referenced material.**

Not Applicable

10. **If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

Not Applicable

II. Fiscal Analysis

11. **Please estimate the increase / decrease in the agency's revenues or expenditures in the current biennium due to this rule.**

This will have no impact on revenues or expenditures.

0.00

This proposed rule will have no impact on revenues or expenditures. It will not change the projected budget of Ohio EPA during the current biennium.

12. **What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?**

Although there is a cost of compliance associated with this rule, we cannot develop an accurate cost of compliance estimate for this rule due to the number of variables involved. The cost will vary depending on the specific circumstances, including the amount and types of hazardous waste that is managed, and the methods used to manage them. These proposed amendments do not add to the cost of compliance with this rule. Compliance is already required by federal regulation.

13. **Does the rule increase local government costs? (If yes, you must complete an RSFA Part B). No**

14. Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C). Yes
15. If the rule imposes a regulation fee, explain how the fee directly relates to your agency's cost in regulating the individual or business.

Not Applicable.

III. Common Sense Initiative (CSI) Questions

16. Was this rule filed with the Common Sense Initiative Office? Yes
17. Does this rule have an adverse impact on business? No

- A. Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business? No

This rule does not directly require a license, permit, or prior authorization to operate. However, an owner or operator of a hazardous waste management facility subject to this rule is also required to comply with additional applicable rules in OAC Chapters 3745-50 to 3745-69, 3745-205, 3745-256, 3745-266, 3745-270, 3745-273, and 3745-279 which may require a license or permit to operate.

- B. Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms? No

This rule does not directly impose a criminal penalty, civil penalty, or another sanction, or create a cause of action for failure to comply. However, an owner or operator of a hazardous waste management facility subject to this rule is also required to comply with additional applicable rules in OAC Chapters 3745-50 to 3745-69, 3745-205, 3745-256, 3745-266, 3745-270, 3745-273, and 3745-279 which may impose consequences for non-compliance.

- C. Does this rule require specific expenditures or the report of information as a condition of compliance? No

- D. Is it likely that the rule will directly reduce the revenue or increase the expenses of the lines of business of which it will apply or applies? No

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Part C - Environmental Rule Questions

Pursuant to Am. Sub. H.B. 106 of the 121st General Assembly, prior to adopting a rule or an amendment to a rule dealing with environmental protection, or containing a component dealing with environmental protection, a state agency shall:

- (1) Consult with organizations that represent political subdivisions, environmental interests, business interests, and other persons affected by the proposed rule or amendment.
- (2) Consider documentation relevant to the need for, the environmental benefits or consequences of, other benefits of, and the technological feasibility of the proposed rule or rule amendment.
- (3) Specifically identify whether the proposed rule or rule amendment is being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal environmental law or to participate in a federal environmental program, whether the proposed rule or rule amendment is more stringent than its federal counterpart, and, if the proposed rule or rule amendment is more stringent, the rationale for not incorporating its federal counterpart.
- (4) Include with the proposed rule or rule amendment and rule summary and fiscal analysis required to be filed with the Joint Committee on Agency Rule Review information relevant to the previously listed requirements.

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- (A) Were organizations that represent political subdivisions, environmental interests, business interests, and other persons affected by the proposed rule or amendment consulted? Yes**

Please list each contact.

Nearly 4000 interested/affected parties were contacted via listserv to invite them to comment on draft rules and inform them of the process that would be used by the agency to obtain input on this rule. In addition, the draft rules were posted on Ohio EPA's website along with an announcement of the opportunity comment on the rules. The list of stakeholders is available upon request.

- (B) Was documentation that is relevant to the need for, the environmental benefits or consequences of, other benefits of, and the technological feasibility of the proposed rule or amendment considered? Yes**

Please list the information provided and attach a copy of each piece of documentation to this form. (A SUMMARY OR INDEX MAY BE ATTACHED IN LIEU OF THE ACTUAL DOCUMENTATION.)

The documents considered in the development of this rule include the equivalent federal counterpart regulation (40 CFR 266.504), the Federal Register documenting the addition

of that federal regulation, the LSC Manual, and the Ohio Revised Code, particularly 3734.12.

- (C) Is the proposed rule or rule amendment being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal environmental law or to participate in a federal environmental program? Yes**

Is the proposed rule or rule amendment more stringent than its federal counterpart?
No Not Applicable

- (D) If this is a rule amendment that is being adopted under a state statute that establishes standards with which the amendment is to comply, is the proposed rule amendment more stringent than the rule that it is proposing to amend? No**