



# Common Sense Initiative

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## Business Impact Analysis

Agency, Board, or Commission Name: Ohio Environmental Protection Agency (Ohio EPA)

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Regulation/Package Title (a general description of the rules' substantive content):

Infectious Waste Rules

Rule Number(s): Ohio Administrative Code (OAC) Rules 3745-27-30, 3745-27-32, 3745-27-33, 3745-27-35, 3745-27-36, 3745-27-37, 3745-27-38, 3745-27-39, 3745-28-01, 3745-28-07, 3745-500-01, 3745-500-02, 3745-500-210, 3745-500-220, 3745-501-05, 3745-550-01 3745-570-01, 3745-570-02, 3745-570-31, 3745-570-100, 3745-570-110, 3745-570-120, 3745-570-125, 3745-570-130, 3745-570-200, 3745-570-201, 3745-570-202, 3745-570-203, 3745-570-204, 3745-570-205, 3745-570-210, 3745-570-211, 3745-570-212, 3745-570-213, 3745-570-219, 3745-570-220, 3745-570-221, and 3745-570-222.

Date of Submission for CSI Review: June 21, 2024

Public Comment Period End Date: July 22, 2024

Rule Type/Number of Rules:

New/ 24 rules

No Change/ 0 rules (FYR?   )

Amended/ 8 rules (FYR? 7 Y, 1 N)

Rescinded/ 8 rules (FYR? Y)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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### **Reason for Submission**

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

**Which adverse impact(s) to businesses has the agency determined the rule(s) create?**

**The rule(s):**

- a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

### **Regulatory Intent**

2. **Please briefly describe the draft regulation in plain language.**

***Please include the key provisions of the regulation as well as any proposed amendments.***

OAC rules 3745-27-30 through 3745-27-39 contain requirements for the management and disposal of infectious waste. OAC rules 3745-28-01 and 3745-28-07 pertain to infectious waste host fees. As part of the review conducted in accordance with Ohio Revised Code (ORC) section 106.03, Ohio EPA has determined that the rules in OAC Chapter 3745-27 would better serve the regulated community if they were reorganized in a new chapter. Many of the rule requirements in current rule will be carried over unchanged to the new rule chapter. Significant amendments incorporated into this review include the following:

- Removing the requirement for a notarized signature from the final closure certification and infectious waste host fee returns.
- Removing the requirement to use a Mycobacteria species to test the performance of alternative infectious waste treatment technologies.
- Including storage timeframes to ensure infectious waste from infectious waste generators is transported to treatment facilities to prevent additional instances of long-term storage and illegal disposal of infectious waste.
- Creating a prohibition for the storage of infectious waste in self-storage units.
- Including the information that is required to be submitted on the large generator registration application in rule and expanding the contact information section to now

identify each premises owned or operated by the generator where infectious waste is generated.

- Incorporating specifications that allow the reuse of sharps containers.
- Incorporating specifications that allow the recycling of treated infectious waste.
- Including standards to allow for the treatment of select agents.
- Expanding the approved treatment methods for treatment facilities to include treatment by ozone exposure.
- Including a 10-year update for alternative infectious waste treatment technology approvals to ensure the technology continues to meet the performance standard for treatment of infectious waste.
- Including a performance standard for a 6 log<sub>10</sub> reduction in bacterial spores for both existing and alternative infectious waste treatment technologies to align with specifications adopted in other states and allow for the use of spore strips that are more easily obtained by the owner or operator of the infectious waste treatment facility. The current rule requires spore strips for a 4 log<sub>10</sub> reduction, which are not as widely manufactured as the 6 log<sub>10</sub> spore strips.

**3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

The infectious waste rules are authorized under Ohio Revised Code (ORC) sections 3734.02, 3734.021, and 3734.026. Statutes that are amplified include ORC sections 3734.02, 3734.021, 3734.023, 3734.024, 3734.025, 3734.026, and 3734.05. “Multi-program” rules in OAC Chapter 3745-500 under review in this package are authorized under ORC sections 3714.02, 3714.022, 3734.02, and 3734.12. Amplified statutes include ORC sections 3714.02, 3714.022, 3714.04, 3714.09, 3734.02, 3734.021, 3734.12, 3734.03, and 3734.08.

**4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

*If yes, please briefly explain the source and substance of the federal requirement.*

No.

**5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

Not applicable.

**6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

The public purpose of these rules is to fulfill the requirements of ORC section 3734.021, which obligates the director to adopt rules governing infectious waste to ensure protection of human health or safety or the environment.

**7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The Agency will measure the success of these regulations through compliance with the infectious waste rules in this package. The reorganization of these requirements increases the efficiency and readability of the rules and will reduce confusion.

**8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

*If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No.

**Development of the Regulation**

**9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

Ohio EPA released an initial early stakeholder outreach (ESO) fact sheet in March 2017 notifying regulated entities and the public that the Agency was seeking input on changes to the rule. Stakeholders were contacted individually by telephone in August 2023 to notify them of the conceptual revisions under consideration and of an upcoming release of another ESO. A subsequent ESO was released in September 2023 to update stakeholders on the progress of the package and give them another opportunity to submit comments on the conceptual revisions. All parties were notified via the Agency listserv system and provided thirty days (September 16, 2023, to October 16, 2023) to comment on the changes being considered in this review. After the ESO, a webinar for stakeholders to discuss the agency's proposed conceptual changes was held on January 17, 2024.

**10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

After the first ESO period, Ohio EPA received comments from two local health departments, Stericycle, the Ohio Funeral Directors Association, and Sharps Compliance, Inc. The Agency considered these comments while working to reorganize the existing regulations. Interested parties that submitted comments on the first ESO were contacted individually prior to the release of the subsequent ESO. Ohio EPA again received feedback from Stericycle during this secondary outreach period. The interested party draft reflects changes that address industry concerns and reflect a streamlined and updated infectious waste program.

**11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

The Agency analyzed current industry practices, inspection data, and evaluated reports submitted by facilities to develop rules that reflect best environmental practices and support

industry standards. The Agency also benchmarked with the State and Territories Association on Alternative Treatment Technologies.

- 12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**  
*Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.*

These rules include specifications for multiple authorized infectious waste treatment methods, as well as a process for obtaining approval for alternative treatment methods, offering options for the owner or operator of an infectious waste treatment facility to choose the one that best suits their business needs.

- 13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

Ohio EPA reviewed our own regulations and performed a search of regulations from other agencies to determine if there was duplication with existing regulations. These rules did not duplicate an existing Ohio regulation.

- 14. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

The Agency plans to continue the current efforts to ensure consistent and predictable rule implementation, including providing education for stakeholders regarding the re-organization of the rules. The selection of rule effective dates will allow time for a smooth transition from OAC Chapter 3745-27 to OAC Chapter 3745-570.

#### **Adverse Impact to Business**

- 15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**

- a. Identify the scope of the impacted business community, and
- b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.*

The scope of the impacted business community includes generators of infectious waste and owners and operators of infectious waste treatment facilities. Although there are costs associated with these rules, any estimate must account for a range of significant variables. The cost will naturally vary depending on how much infectious waste the generator produces

monthly. Generators that produce less than fifty pounds per month are eligible for the exclusion to register with Ohio EPA and are responsible mainly for the cost to package the infectious waste for proper disposal with the municipal trash. “Large generators,” or those that produce fifty pounds or more per month, are subject to a three-year registration that includes a \$140 fee. An owner or operator of an infectious waste treatment facility is subject to costs associated with preparing and submitting a permit to install application and obtaining an annual license. Expenditures will vary depending on the size, design, and location of the infectious waste treatment facility. In addition to permitting and licensing costs, an owner or operator of an infectious waste treatment facility will incur business expenses to conduct operations at the facility including performing validation testing and biological challenge testing for the treatment unit to ensure it is meeting the specified performance standard. These too are variable, with the majority of the cost incurred through the purchase of spore strips. Commercially available spore strips average around \$350 for a pack of 100. The number of spore strips needed is determined by the infectious waste treatment facility’s throughput, which is based on the volume authorized by Ohio EPA and the owner or operator’s decision on how much infectious waste to treat. Finally, expenditures to close the facility upon cessation of operations will factor into the overall cost of compliance.

ORC Chapter 3734 establishes the fee amounts for permits to install and annual licenses. A \$400 permit to install application fee is required upon submittal of a permit to install application and is credited to the permit fee upon issuance. The permit fee for an infectious waste treatment facility or solid waste incinerator that treats infectious waste ranges from a minimum of \$1,000 to a maximum of \$80,000 based whether the facility is new or existing and if the permit is for an increase in facility’s treatment capacity. Infectious waste treatment facilities, other than those treating infectious waste by means of incineration, are subject to an annual license fee that ranges from a minimum of \$5,000 to a maximum of \$60,000. Solid waste incinerators (including those authorized to treat infectious waste) range from a minimum of \$2,500 to a maximum of \$30,000 based upon the tonnage of authorized maximum daily waste receipt. All solid waste licenses include a \$100 application fee, which is credited to the license fee upon issuance.

**16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. *(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

The Agency removed the requirement for an owner or operator of an infectious waste treatment facility to test the performance of an alternative infectious waste treatment technology using a Mycobacteria species. This reduces the overall amount of testing that must be conducted for new technologies and lowers the cost of obtaining approval to use the technology in Ohio. The Agency also added provisions for the reuse of sharps containers that do not exist in current rule. These reuse provisions will decrease the cost to generators by reducing the number of sharps containers that must be purchased. These provisions will also lessen the burden for infectious waste treatment facilities by decreasing the amount of waste that is required to be disposed, thus saving on disposal costs. The option to reuse sharps

containers also allows the generator and the owner or operator of the infectious waste treatment facility to increase their sustainability efforts.

**17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

Infectious waste has the potential to transmit disease and impose other impacts on human health. To ensure infectious waste is properly managed, the Agency is required to adopt rules pursuant to ORC section 3734.021. The regulatory intent and statutory mandate justify the adverse impact to the regulated business community.

**Regulatory Flexibility**

**18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

Any person subject to the infectious waste regulations contained in this package has the option to submit a variance request in accordance with ORC 3734.021 or an exemption request in accordance with ORC 3734.02(G) as an alternative means of compliance. These rules also provide the owner or operator of an infectious waste treatment facility the option to apply for and receive approval for an alternative treatment technology in lieu of those pre-approved in OAC Chapter 3745-570. Small generators of infectious waste are generally permitted to manage the infectious waste in the same manner as solid waste instead of transporting the infectious waste for treatment.

**19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

The director or the approved health department will evaluate the applicability of ORC section 119.14 to persons subject to the infectious waste rules in this package when assessing fines and penalties for paperwork violations and first-time offenders.

**20. What resources are available to assist small businesses with compliance of the regulation?**

Ohio EPA's Office of Compliance Assistance and Pollution Prevention (OCAPP) is a non-regulatory program that provides information and resources to help small businesses comply with environmental regulations. OCAPP also helps customers identify and implement pollution prevention measures that can save money, increase business performance, and benefit the environment. Services of the office include a toll-free hotline, on-site compliance and pollution prevention assessments, workshops/training, a plain-English publications library, and assistance in completing permit application forms. Additional information is available at: <http://epa.ohio.gov>.