

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Environmental Protection Agency (Ohio EPA)

Regulation/Package Title: Infectious Waste Rules

Rule Number(s): 3745-27-01, 3745-28-01, 3745-27-30, 3745-27-31, 3745-27-32, 3745-27-33, 3745-27-34, 3745-27-35, 3745-27-36

Date: August 9, 2012

Rule Type:

- | | |
|---|---|
| <input type="checkbox"/> New | <input checked="" type="checkbox"/> 5-Year Review |
| <input checked="" type="checkbox"/> Amended | <input checked="" type="checkbox"/> Rescinded |

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

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

These regulations identify requirements for the generation, treatment, packaging, labeling and transport of infectious waste. Proposed amendments to these rules include the changes to the statute as a result of Senate Bill 294.

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2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

Ohio Revised Code 3734.01, 3734.02, 3734.021, 3734.05, 3734.06.

3. Does the regulation implement a federal requirement?

The proposed regulations are being amended in principle to remove the duplication of 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?** No.

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

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

5. 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 purpose of these regulations is to provide a common sense approach to manage infectious waste and limit transmission and exposure to infectious agents.

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

The removal of duplication in the regulations allows for greater success for small businesses releasing them from the burden of complying with two sets of overlapping rules. Continued minimal complaints regarding infectious facility operation, continued minimal violations of environmental laws, and the absence of environmental and health impacts are also Agency measures of success.

Development of the Regulation

7. 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.

There were a series of meetings that occurred from September 2009 until July 2012 with the Ohio Hospital Association, the Ohio Veterinary Medical Association, the Ohio Dental Association, the Ohio Funeral Directors Association, the Ohio Academy of Nursing Homes and numerous other associations and stakeholders. These interested parties collaborated to amend the authorizing statute. Stakeholders will be notified of the draft rules via an Agency listerv message and a message from the State of Ohio's eNotification system.

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

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Input from the stakeholders focused on infectious waste transporters and the packaging of infectious waste, and was provided through the legislative process in consideration of Senate Bill 294. These rules reflect changes in the authorizing statute.

9. 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 use of new scientific data was not used in this rulemaking effort; however the infectious waste treatment and management rules use a scientific basis consistent with industry standards. The remaining requirements in these rules are derived directly from statute.

10. 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?

Federal preemption statutes regarding transportation of infectious substances eliminated the need for overlap in state rules. There are no options for alternate regulations. The amendments to the generator requirements in this rulemaking not only considered the alternatives but implemented them. The Agency chose to remove duplicative transportation requirements and allow regulated entities to follow only the Occupational Safety and Health Administration and Public Utilities Commission of Ohio and the U.S. Department of Transportation standards.

11. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

No, the Agency reduced unnecessary duplication of the rules. This decision could be seen as an attempt to create a performance-based process for regulated stakeholders by allowing them to only comply with one set of federal regulations regarding the transportation of infectious wastes.

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

The Agency removed all duplication with the Occupational Safety and Health Administration and Public Utilities Commission of Ohio regulations.

13. 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.

Through the legislative process, broad notice was provided to regulated entities. The Agency will separately provide notice to registered transporters and infectious waste generators to inform them of regulatory changes. The deletions of the duplicative rules will allow a more consistent application of the infectious waste rules that remain in effect with the Public Utilities Commission of Ohio, U.S. Department of Transportation and the Occupational Safety and Health Administration.

Adverse Impact to Business

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14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The impacted business community includes infectious waste generators, transporters, and owners or operators of infectious waste treatment facilities.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

There are license fees for treatment facilities, registration fees for generators and fines for non-compliance, all of which are established in the statute. Infectious waste transporter fees will be eliminated through the revisions to these rules.

c. Quantify the expected adverse impact from the regulation.

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.

Large quantity infectious waste generators (those producing 50 pounds or more per month) have a statutory fee of \$140 every three years. This fee covers all premises that the registered generator owns. The Cleveland Clinic Foundation has 111 premises and they pay \$140. Laboratory Corporation of America has 126 premises and they pay \$140.

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

The statute is very explicit to elements of the regulatory program. The rules are structured to implement the statute. This rulemaking reduces the adverse impact on business. The statute lowered the registration application fee from \$300 to \$140 reducing the adverse impact to the business community.

Regulatory Flexibility

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

An owner or operator of an infectious waste facility subject to the regulations contained in Ohio Administrative Code 3745-27 are also required to comply with rules 3745-27-01, 3745-27-02, 3745-27-03, 3745-27-04 and 3745-27-05 of the Administrative Code. Rule 3745-27-03 pertains to exemptions and variations that allow for alternative means of compliance.

17. 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 infectious waste facilities regulated under OAC Chapter 3745-27 when assessing fines and penalties for paperwork violations and first-time offenders.

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18. 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, plain-English publications library and assistance in completing permit application forms. Additional information is available at: <http://epa.ohio.gov>.