Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

MEMORANDUM

TO: Mandi Payton, Ohio Environmental Protection Agency

FROM: Caleb White, Business Advocate

DATE: October 16, 2024

RE: **CSI Review – Infectious Waste Rules (OAC 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)**

On behalf of Lt. Governor Jon Husted, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Agency as provided for in ORC 107.54.

Analysis

This rule package consists of twenty-four new rules, eight rescinded rules, and eight amended rules proposed by the Ohio Environmental Protection Agency (OEPA) as a part of the statutory five-year review process. This rule package was submitted to the CSI Office on June 21, 2024, and the public comment period was held open through July 22, 2024. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on June 21, 2024.

The rules in this package are being submitted as a part of a reorganization of infectious waste rules. Ohio Administrative Code (OAC) 3745-27-30, 3745-27-32, 3745-27-33, 3745-27-35, 3745-27-36, 3745-27-37, 3745-27-38, and 3745-27-39 are to be rescinded and their contents moved to a new chapter to be created for the regulation of infectious waste. These rules pertain to standards and requirements for the generators of infectious waste, standards and requirements for the operation of

infectious waste treatment facilities, disposal paper requirements, standards and requirements for the handling of infectious waste, the registration requirements for the generators of infectious waste, the process and requirements for an infectious waste facility's permit to install application, the approval process and requirements for the approval of alternate infectious waste treatment technology, and the process and requirements for the closure of an infectious waste treatment facility. This package also contains two new rules, OAC 3745-27-32 and 3745-27-37, which replace two rescinded rules for the purpose of directing references in other sections of the OAC to the appropriate rule in the newly created chapter.

These new rules differ from the rescinded rules by removing aa notarization requirement, removing a requirement for the use of Mycobacteria species for the purpose of testing alternative infectious waste treatment technologies, adding waste storage timeframes, adding a prohibition on storing infectious waste in self-storage units, adding additional information to be included in large generator registration applications, allowing the reuse of sharps containers under certain conditions, adding standards for the treatment of certain agents, allowing ozone exposure to be used as a treatment method, updating the alternative infectious treatment technology approvals, and increasing the performance standard for reduction in bacterial spores from a 4 $\log_{10}$ to a 6 $\log_{10}$ reduction.

During the initial early stakeholder outreach, the OEPA released a factsheet in March of 2017 that requested feedback on changes to the rules. The OEPA then individually contacted stakeholders via telephone in August of 2023 to notify them of the conceptual revisions to the rules. In September of 2023, the OEPA conducted a second early stakeholder outreach period to request further feedback on the proposed revisions beginning on September 16, 2023, and ending on October 16, 2023. The OEPA then conducted a webinar for stakeholders on January 17, 2024, to discuss the proposed rules. During the first early stakeholder outreach period, the OEPA released a factsheet in March of 2017 which notified stakeholders that they were seeking input on the changes to the rules. After the initial outreach, the OEPA contacted stakeholders by telephone in August of 2023 to give them the conceptual changes to the rules. The OEPA then opened the rules up to a comment period beginning on September 16, 2023, and ending on October 16, 2023. Finally, the OEPA conducted a webinar to discuss the proposed changes on January 17, 2024. During this period the OEPA received comments from local health departments Stericycle, the Ohio Funeral Directors Association, and Sharps Compliance, Inc and incorporated changes into the rules in response to some of the concerns raised by stakeholders.

During the CSI public comment period, the OEPA received two comments. One comment came from Stericycle and the other comment came from the Healthcare Waste Institute (HWI). The comment from Stericycle requested adding "substantial" through OAC 3745-570-02. The OEPA responded to this comment by stating that this would add confusion and ambiguity to the rule and elected not to make this change. Next Stericycle commented that OAC 3745-570-31 only addressed chemical

options when hot water treatment options for the reuse of containers are also approved in other states. In response to this the OEPA amended the rule to allow for the use of water at 180 degrees Fahrenheit for a minimum time of fifteen seconds after the containers have been washed to remove any debris. Stericycle also pointed out an incorrect reference in OAC 3745-570-31 which the OEPA corrected. Next, Stericycle asked for an explanation in changing the recordkeeping requirements in OAC 3745-570-200 from three to five years. The OEPA clarified this change to be consistent with other records requirements and to reflect the minimum requirements in statute. Stericycle then asked for regulations for hazardous waste pharmaceuticals to be either incorporated or referenced as sometimes generators may inadvertently send hazardous waste to an infectious waste treatment facility. The OEPA did not make this change as the referenced rules contain very limited exemptions and do not exclude materials or persons from infectious waste requirements. Stericycle also asked for clarification on why every load of treated waste that is to be recycled is required to be tested. The OEPA responded that recycling infectious waste is a new concept in Ohio and there is no widely accepted practice. Therefore, this requirement is necessary for the receiving facility to have confidence that the waste is safe to manage. Stericycle opposed the changing of the performance standard for reduction in bacterial spores in OAC 3745-570-203 from a 4 $\log_{10}$ to a 6 $\log_{10}$ reduction, as this is not used in other states. The OEPA responded by stating that this new standard is being adopted to offset the overall reduction in the number of bacteria must be tested for and did not make changes in response to this comment. Finally, Stericycle requested the requirements for validation testing and quality assurance in OAC 3745-570-203 be reduced to be less burdensome. The OEPA responded to this comment by including bins in the calculation for total treatable volume. HWI asked that OAC 3745-570-31 be split into two sections to clarify responsibilities. The OEPA did not make this change as this would lead to unnecessary duplication of requirements.

Both commenters suggested amending the applicability section in 3745-550-01 to clarify language as two provisions in the rule appear to be the same, recommended requiring ridged containers for all sharps waste, and requiring healthcare providers to be responsible for all trace chemotherapy wastes. The OEPA responded that the two provisions referred to by the commenter address two different instances consistent with statute and that requiring healthcare providers to manage non-infectious wastes is beyond the scope of the rules. Accordingly, the agency did not make any changes to this comment. Next, the commenters asked for the sixty-day storage time limit in OAC 3745-570-31 to be clarified. In response to this comment the OEPA moved this time limit to OAC 3745-570-100 to clarify that it is the generator's responsibility to ensure compliance with this requirement. Next, both commenters asked that the fourteen-day storage time limit at treatment facilities in OAC 3745-570-31 be expanded to thirty days for non-putrescible infectious waste and refrigerated putrescible infectious waste. The OEPA did not make this change as this ensures waste is maintained in a non-putrescent manner. Both commenters also requested adding a seven-day storage time limit for transporters of infectious waste to OAC 3745-570-31. The OEPA did not make this change as they do not regulate the transportation of infectious waste. Next, the commenters requested the deletion

of limits for storage volumes in OAC 3745-570-31 as this puts an unnecessary burden on facilities. The OEPA did not make this change as this limit refers to the total authorized capacity of all treatment units in the entire treatment facility, and in a special circumstance a facility can seek a variance or seek to modify their permit. Commenters additionally asked for requirements for the incineration of trace chemotherapy and non-hazardous pharmaceutical waste before final disposal to be added to OAC 3745-570-31. The OEPA did not make this change as chemotherapy wastes and pharmaceuticals are regulated by other state and federal regulations. Another comment expressed by both parties was for training requirements in OAC 3745-570-31 to be expanded to apply to generators and transporters. The OEPA did not make this change as they do not regulate the transportation of infectious waste, adding that the annual training required under federal bloodborne pathogen regulations for generators should be sufficient. The final set of shared comments requested the monthly biological challenge testing for autoclaves in OAC 3745-570-203 be changed to every six months as monthly testing is overly burdensome and unnecessary. The OEPA did not make changes in response to this comment as this requirement is consistent with that of other states. After issuing the response to comments, OEPA also met with Stericycle to discuss the rules and provide clarification. Following that discussion, OEPA staff informed CSI that the stakeholder indicated its support of the proposal as drafted.

The business community impacted by the rules includes generators of infectious waste and owners and operators of infectious waste treatment facilities. The adverse impacts created by the rules include the costs associated with packaging infectious waste, registration fees, licensure requirements, the costs associated with obtaining a permit to install, testing requirements, and facility closure requirements. The Department states that the fees can include a $400 permit to install application fee, a $140 three-year registration fee, a permit fee for an infectious waste treatment facility or solid waste incinerator that treats infectious waste which can range from $1,000 to $80,000, an annual license fee that can range from $5,000 to $60,000 for infectious waste treatment facilities and from $2,500 to $30,000 for solid waste incinerators, and a $100 application fee. The OEPA further states that the overall adverse impacts will vary based on certain factors such as how much waste a generator produces. The OEPA notes that several changes in the rules will reduce the adverse impacts to business. These changes include removing a requirement for the testing of the performance of an alternative infectious waste treatment technology and allowing the reuse of sharps containers. The OEPA states that the adverse impacts to business are justified to fulfill the OEPA's statutory requirement to regulate infectious waste and ensure protection of human health, safety, or the environment.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that the OEPA should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.