

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Health (ODH)

Regulation/Package Title: Reportable Infectious Diseases

Rule Number(s): 3701-3-02.1, 3701-3-02.2, 3701-3-08, 3701-3-10, 3701-3-12, 3701-3-13, 3701-3-28, and 3701-3-29 are 3701-13-30 (Rules 3701-3-13 and 3701-3-30 will be proposed without change)

Date: December 10, 2013

Rule Type:

New
☒ Amended

☒ 5-Year Review
Rescinded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.

These rules relate to infectious diseases that the Ohio Department of Health monitors for public health purposes. 3701-3-02.1 is a rule regarding the reporting of occupational diseases; 3701-3-02.2 is a rule regarding the notification of emergency

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medical service workers if they may have been exposed to a disease that poses an occupational risk; 3701-3-08 is a rule allowing public health to view medical records as needed for public health investigation and to prevent further disease transmission; 3701-3-10 is a rule regarding the Director's approval of HIV tests for diagnosis of HIV infection; 3701-3-12 is a rule regarding AIDS and HIV test reporting; 3701-3-13 is a rule regarding isolation requirements for specific infectious diseases; 3701-3-28 is a rule requiring the reporting of animal bites to public health for public health monitoring; 3701-3-29 is a rule regarding how animals that have bitten people should be handled as part of rabies prevention and control and 3701-3-30 is a rule regarding the reporting of suspected rabid mammals.

Please list the Ohio statute authorizing the Agency to adopt this regulation. **R.C. 3701.23, 3701.13, 3701.241, 3701.248, and 3701.25**

2. Does the regulation implement a federal requirement? **No.** 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.**
3. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement. **While the federal government does not require infectious disease reporting, much of ODH's federal funding is tied to and predicated on data and actions taken from infectious disease reporting.**
4. 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) **Reporting the incidents of infectious disease is necessary to prevent and control the spread of those diseases in Ohio and to fulfill the public health duties in R.C. 3701.13 and 3701.14.**
5. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes? **ODH uses the data to target prevention measures with the intent to reduce the burden of disease in Ohio. Success is measured in controlling, slowing, and to the extent possible, preventing the spread of disease**

Development of the Regulation

6. 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.*

Local Health Districts (LHDs), hospitals, physicians, the Department of Public Safety (for rule 3701-3-02.2), and other health professionals, including veterinarians, were engaged via telephone conference and face-to-face meetings.

7. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?
The draft rules were created based on comments and scientific data. The rule regarding the reporting of occupational diseases is now consistent with statutory requirements.
8. What scientific data was used to develop the rule or the measurable outcomes of the rule? ODH models its rules based on the United States Centers for Disease Control and Prevention (CDC) public health guidance and recommendations. The rules pertaining to HIV tests and reporting need to be updated and the proposed changes are consistent with CDC guidance. Scientific literature regarding disease transmission to healthcare workers was used for 3701-3-02.2. Ohio Veterinarian Medical Association standards guided the proposed changes to 3701-3-28 and 3701-3-29.

How does this data support the regulation being proposed? The proposed rules will be consistent with CDC recommendations and the state of the science.

9. 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?
The Agency did not consider alternative regulations as CDC is the national standard for public health guidance and recommendations.
10. 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. LHDs monitor timeliness and completeness of disease reporting. It is important that the reporting process is standardized and consistent with CDC guidance.
11. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation? ODH is the only state agency authorized to control and suppress the spread of infectious diseases in humans.
12. 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. Who and how will ODH be notifying the affected parties that there was a change? ODH will notify its LHD partners via conference call; ODH will send

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email notification to hospitals, laboratories, and other applicable health professional organizations (e.g. Ohio veterinarians).

Adverse Impact to Business

13. 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: **Hospitals, clinics, physician offices, labs, and veterinarians.**
 - b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); **Reporting requirements stay the same – the changes that are proposed simplify the language for the rules. And,**
 - c. Quantify the expected adverse impact from the regulation. **Negligible.**
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. Reporting requirements stay the same – the changes that are proposed simplify the language for the rules.
14. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community? **The core mission of public health is to promote the health of all Ohioans. See R.C. 3701.13. To achieve this mission, public health has always required the reporting of dangerous infectious or contagious diseases so that public health can take the appropriate action. See R.C. 3701.23. However, as the science of medicine has evolved over time, public health has had to adjust from time to time which diseases are to be reported, how the diseases are to be diagnosed, and what control measures need to be implemented to prevent disease transmission. The activities that are undertaken by the proposed rules simplify the language for the rules and modify the rules to meet current public health practice.**

Regulatory Flexibility

15. Does the regulation provide any exemptions or alternative means of compliance for small businesses? **No. Please explain. There is no viable alternative to provider-initiated reporting at this time. Without reporting ODH has no mechanism to determine the burden of the diseases.**
16. 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? ODH does not issue fines for minor paperwork violations or for first-time offenders.

- 17. What resources are available to assist small businesses with compliance of the regulation? Anyone needing assistance may call a LHD or ODH representative.**