

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Health

Regulation/Package Title: Infectious Diseases

Rule Number(s): 3701-3-02, 3701-3-11, 3701-3-15, 3701-73-01, 3701-73-02

Date: January 20, 2015 - Revised

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☐ Rescinded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.

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

The rules refine the Revised Code's mandatory reporting of certain infectious diseases to public health authorities. The proposed changes to this rule specifically list diseases but the actions that individuals have to take regarding the diseases stay the same as they currently are. Listing of the disease removes any potential confusion about whether the diseases are reportable (as the diseases are reportable even though they are not specifically mentioned). The rules indicate what information is relevant and accessible to public health authorities.

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Finally, rule 3701-73-02 sets forth the criteria for the imposition of fine in the case when a mandatory reporter fails to report a required disease.

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

Rule 3701-3-02 is authorized by R.C. 3701.23
Rule 3701-3-11 is authorized by R.C. 3701.241
Rule 3701-3-15 is authorized by R.C. 3701.232
Rule 3701-73-01 is authorized by R.C. 3701.13
Rule 3701-73-02 is authorized by R.C. 3701.571

3. 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.

These rules do not implement federal requirements.

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 Ohio Department of Health shall have supervision of all matters relating to the preservation of the life and health of the people and have ultimate authority in matters of quarantine and isolation, which it may declare and enforce, when neither exists, and modify, relax, or abolish, when either has been established. R.C. 3701.13. The Director of Health shall investigate or make inquiry as to the cause of disease or illness, including contagious, infectious, epidemic, pandemic, or endemic conditions, and take prompt action to control and suppress it. R.C. 3701.14(A). Without mandatory reporting by the individuals diagnosing and treating the identified diseases, public health authorities couldn't carry out their mission.

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

The success of these rules is evidenced by the prompt reporting and cooperation of the individuals diagnosing and treating the identified diseases.

Development of the Regulation

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

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

The Ohio Department of Health's stakeholder outreach included local health departments, infectious disease physicians, and hospital infection preventionists.

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

Stakeholders affirmatively supported the clarifications in amended rule 3701-3-02 and supported not making changes to the other rules.

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 diseases reportable in Ohio are nationally notifiable to the United States Centers for Disease Control and Prevention. Thus, the reporting list is the same for the entire country.

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?

Alternatives are not available as the reporting obligations are set forth in the Revised Code. The Ohio Department of Health limits requested data to the minimum necessary to accomplish its public health mission.

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.*

Performance-based compliance is not an option as the specified diseases of public health interest must meet the specific definitions for each disease. Because of the potentially serious impact of the identified diseases prompt and precise reporting is critical.

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

Pursuant to R.C. 3701.13, the Ohio Department of Health shall have supervision of all matters relating to the preservation of the life and health of the people and have ultimate authority in matters of quarantine and isolation. No other state agency has this authority.

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.

The authorizing statutes give the Director of Health the authority to prescribe the manner in which the reporting is to be accomplished. The Director of Health has published the Ohio

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Infectious Disease Control Manual on the agency website outlining the appropriate responses measures and what information must be reported to public health authorities. All mandatory reporters are encouraged to report through electronic reporting systems.

Adverse Impact to Business

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

Local health departments, hospitals, and other providers are reporting infectious diseases under the current rules. Their work will not change with the proposed rule changes in rule 3701-3-02. The changes are to clarify the specific diseases that are reportable and to make sure that there isn't any confusion about several reportable diseases. (Several reportable diseases are reportable under categories, but this specifically lists the diseases by name to ensure clarity.) The other rules in the package are being proposed as no change.

Rule 3701-73-02 sets out a graduated fine system for not complying with a public health reporting requirement. The fines are based on a matrix involving the public health impact of the non-reporting and the history of the provider's prior compliance. The potential fine ranges from one hundred to seven hundred fifty dollars per incident of non-reporting.

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

Any impact is created by the Revised Code. The Department of Health has worked to minimize the scope and severity of the impact by request only the minimum amount of information necessary to accomplish the public health mission.

Rule 3701-73-02 is being reviewed pursuant to the five-year rule review and being proposed as “no change.” RC 3701.571(A) instructs the Director of Health to adopt a rule establishing “a graduated system of fines based on the scope and severity of violations and the history of compliance, not to exceed seven hundred fifty dollars per incident” on anyone who fails to comply with a public health reporting requirement. The rule seeks to fulfill the General Assembly's mandate in an equitable and predictable manner.

Regulatory Flexibility

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

A state agency cannot exempt or alter in the Administrative Code obligations imposed by the Revised Code.

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?

Fines are imposed by R.C. 3701.571; however, the fine structure created in rule 3701-73-02 uses a matrix based on the violator's previous history and the severity the non-reporting had on disease control measures. The goal is compliance rather than being punitive; accordingly, the Director of Health may not seek to impose a fine if future compliance is assured. For this reason, "Unless otherwise demonstrated, a health care provider who submits electronic reports in the manner approved by the director shall be presumed compliant...." Rule 3701-3-03(A)(2).

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

The Department of Health has staff available to assist reporters. While there is a preference in public health and the provider community for electronic reporting, reports can be taken verbally and in writing via a postage service or facsimile.