

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, 3701-3-05, and 3701-3-06

Date: December 21, 2012

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☐ Rescinded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 identify infectious diseases and the requirements for reporting them to the Ohio Department of Health in a timely manner.
2. Please list the Ohio statute authorizing the Agency to adopt this regulation. **3701.23**

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3. 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**
4. 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 infectious disease reporting.**
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 this rule is to identify which infectious or contagious diseases are to be reported by healthcare providers, R.C. 3701.23(B)(5), in order to prevent and control the spread of infectious disease in Ohio and to fulfill the duties set forth in R.C. 3701.13 and 3701.14.**
6. 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.**

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.
Local Health Districts (LHD), hospitals, physicians, clinics, and other health professionals

If applicable, please include the date and medium by which the stakeholders were initially contacted.
8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency? **Based on comments from the LHDs and other constituents, removing certain diseases from the list was postponed.**
9. What scientific data was used to develop the rule or the measurable outcomes of the rule? **The matter was considered by the Council of State and Territorial Epidemiologists (CSTE) (i.e., what infectious diseases should be required to be reported to CDC.) How does this data support the regulation being proposed? The CSTE recommendations were adopted by CDC; ODH follows CDC guidelines.**
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? **N/A.** If none, why didn't the Agency consider regulatory alternatives?

Because 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.

11. Did the Agency specifically consider a performance-based regulation? Please explain.
There is no performance –based standard for disease reporting. To ensure the receipt of consistent, accurate, and actionable information, the reporting process must be standardized.
Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.
12. 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 regulate infectious diseases.
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. Who and how will ODH be notifying the affected parties that there was a change? Via conference calls with LHD partners, email notification to hospitals, healthcare providers, and laboratories and other applicable health professional organizations.

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: Hospitals, clinics, physician offices, and labs
 - b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and
Health care providers will need to incur a small cost in adjusting electronic reporting systems and to train employees on the new reporting requirements.
 - 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. ODH reached out to the largest reporting health professional communities to determine if there would be any cost or impact. . ODH reached out to Lab Corp and Qwest Diagnostics, two large diagnostic laboratories that would need to adjust their electronic reporting system to delete and add the diseases per our changes. After repeated attempts, ODH has not

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received any feedback. ODH also reached out to the Ohio Hospital Association who recommended that ODH contact a few hospitals for feedback. ODH then contacted a few infection practitioners (IPs). One comment that we received was “Deleting or adding diseases or changing the names probably won’t affect us much.” Another comment did not respond to the changes directly but requested that ODH assist the IPs with automating the reporting as much as possible as the IPs have many roles and responsibilities in the hospitals and this would be of great assistance. ODH is participating in the development of Electronic Health Information Exchanges and assisting in facilitating the federal “meaningful use of electronic health records” initiative. Based on the feedback, ODH believes the cost of compliance is negligible.

15. 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 public health can take the appropriate action. See Id. and R.C. 3701.23. However, as the state of the science in medicine has evolved over time, public health has had to adjust from time to time which diseases are to be reported. See Id. The purpose of this rule is to identify which diseases are of interest to public health in order to control and prevent infectious those diseases in Ohio.

Regulatory Flexibility

16. 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. As the use of electronic health records becomes more wide-spread, the cost will diminish significantly through automation. However, universal adoption may be as much as ten years away. Until then, all healthcare providers are required to report. Without reporting ODH has no mechanism to determine the burden of the diseases.
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? ODH does not issue fines for minor paperwork or fist-time offenders.
18. What resources are available to assist small businesses with compliance of the regulation? Anyone needing assistance may call a LHD or ODH representative.