

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Health (ODH)

Regulation/Package Title: Tuberculosis

Rule Number(s): 3701-15-01, 3701-15-02, and 3701-15-03

Date: May 15, 2013

Rule Type:

New

X 5-Year Review

X Amended

Rescinded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 provide a framework that aligns national public health practice and medical management standards of care with responsibilities outlined in Ohio Revised Code 339.71 through 339.89.

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

R.C. 3701.146(B)

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

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, but see the response to question 4.

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 and predicated on infectious disease reporting. Currently, ODH receives an average of \$1.2 million federal dollars through the Centers for Disease Control and Prevention (CDC) TB Cooperative Agreement to support activities associated with TB prevention and control. These funds support 5.2 FTE responsible for statewide surveillance, technical support, training, case management and laboratory testing. Four counties (Cuyahoga, Franklin, Hamilton and Montgomery), report 50% of all TB cases in Ohio and receive an average combined total of \$500,000 annually.

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)**

Reporting of tuberculosis is necessary to prevent and control the spread of disease in Ohio and to fulfill the public health duties in R.C. 339.71 through 339.89 and 3701.13 and 3701.146.

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

ODH uses the surveillance and case management data to target prevention measures with the intent to reduce the burden of disease in Ohio and prevent the development of drug resistant strains of TB. Success has and will continue to be measured by a decrease in the incidence of TB in Ohio, as reflected in surveillance data.

Development of the Regulation

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

County TB Control Units, hospitals, physicians and clinics were provided copies of the rules and a request for comments via email March 29, 2013 and April 15, 2013.

8. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?** Four agencies provided comment; Columbus Public Health and Public Health; no opposition to update
Dayton and Montgomery County; no opposition to update
Hamilton County General Health District provided comment on laboratory turnaround time for organism identification outlined in 3701-15-02 (2) (b) (ii)“This is vague. If this includes MTD/RNA probe, yes we do receive results within this time frame. If MTB identification refers only to culture confirmation that typically takes 6-8 weeks.”
Mercy Regional Medical Center, Lorain County; no opposition to update

Comments for 3701-15-02 (2) (b) (ii) were considered. Laboratory turnaround times are consistent with national standards set by the Association of Public Health Laboratories.

9. **What scientific data was used to develop the rule or the measurable outcomes of the rule?**

As required by R.C. 339.73 and R.C. 3701.146, Ohio uses the testing and treatment guidelines set forth by the United States Centers for Disease Control and Prevention (CDC) or the American Thoracic Society. The CDC guidelines have been endorsed and adopted by the American Thoracic Society so that there is only one national standard for Ohio adopt.

How does this data support the regulation being proposed?

The historic and medical research has demonstrated that without public health intervention as set forth in the guidelines, an individual with active pulmonary TB goes on to infect 10-15 people. In the U.S., TB prevention and control activities have prevented over 20,000 new cases of TB over the last 20 years.

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?**

The agency did not consider alternative regulations as there is no reasonable alternative for determining the burden of disease in Ohio and no alternative to the national standard of care.

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.**

There is no performance-based standard. To ensure accurate and consistent reporting and investigation, the manner and methods must be standardized. Reporting data variables are standardized nationally.

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 control and suppress the spread of infectious diseases in humans, including TB.

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?***

Not applicable; this is a 5 year review.

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 for reporting; time spent by employees. Local TB control units- surveillance and case management; time spent by employees time.

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

Employer time for reporting to meet compliance.

- c. **Quantify the expected adverse impact from the regulation.**

These rules are being filed with only a minor change, by including new medical guidelines that were released by CDC in 2011. This new guideline allows for the use of an alternative treatment regimen not included in previously released guidance. Any impact would remain unchanged. Early identification of infectious disease prevents further transmission in the community.

- d. **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.** In most counties, TB is part of a larger infectious disease program where costs are not broken out from the overall budget. Each year, roughly half of all reported TB cases reside in metropolitan areas and the remaining cases are distributed randomly in rural counties. The allocation of resources is largely driven by TB morbidity in any given year and varies according to county.

15. **Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?** The purpose of this rule is to control and prevent

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

infectious diseases, specifically TB, in Ohio. The Ohio General Assembly structured the authorizing statutes to require the adoption and implementation of the national standards for TB surveillance and care as set forth by the CDC. The rules achieve this requirement in the most effective and efficient manner available.

Regulatory Flexibility

16. **Does the regulation provide any exemptions or alternative means of compliance for small businesses? No. Please explain.** All healthcare providers are required to report all suspected and confirmed cases of TB. Without reporting ODH has no mechanism to determine the burden of the diseases, and cannot provide guidance to local TB control unit or medical providers for appropriate infection control measures and treatment standards of care.
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 errors or first-time offenders.
18. **What resources are available to assist small businesses with compliance of the regulation?** Technical assistance is provided to clinical providers by local TB programs and ODH. ODH contracts with an internationally recognized expert in treatment of TB to medically consult with clinical providers for complex cases. Consultation is available for all Ohio residents at no cost.