



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Health (ODH)

Rule Contact Name and Contact Information:

Sarah Mitchell – (614) 387-0652 or Sarah.Mitchell@odh.ohio.gov

Regulation/Package Title (a general description of the rules' substantive content):

Tuberculosis (TB) standards

Rule Number(s): 3701-15-03

Date of Submission for CSI Review: 01/10/2020

Public Comment Period End Date: 02/10/2020

Rule Type/Number of Rules:

New/___ rules

X No Change/___ rules (FYR? ___)

X Amended/ 1 rules (FYR? ___)

Rescinded/___ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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

CSIPublicComments@governor.ohio.gov

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**

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

These rules establish standards for tuberculosis management as described in Ohio Revised Code 339.71 through 339.89. Ohio Administrative Code 3701-15-03 is being revised to incorporate new national medical guidelines released by the Centers for Disease Control and Prevention (CDC) and the American Thoracic Society (ATS).

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

R.C. 3701.146 Duties and powers regarding tuberculosis

4. **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.

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

CSIPublicComments@governor.ohio.gov

- 5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

Not Applicable

- 6. 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)?**

Tuberculosis standards are 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, 3701.13 and 3701.146.

Under 3701.146, (1) The director shall adopt rules establishing standards for the following:

(a) Performing tuberculosis screenings; (b) Performing examinations of individuals who have been exposed to tuberculosis and individuals who are suspected of having tuberculosis; (c) Providing treatment to individuals with tuberculosis; (d) Preventing individuals with communicable tuberculosis from infecting other individuals. The Ohio Department of Health (ODH) follows medical guidelines for TB established by the CDC and ATS, which have recently been revised.

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

ODH uses the statewide disease surveillance system to track and monitor TB cases in Ohio. The success of these rules is evidenced by documented completion of TB treatment in the electronic Ohio Disease Reporting System and no additional reported TB cases among close contacts, indicating effective control measures.

- 8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

Not Applicable

Development of the Regulation

- 9. 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.

Stakeholder outreach included local TB Control Units, physicians, and clinics.

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

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

CSIPublicComments@governor.ohio.gov

Stakeholders supported the revisions in amended rule 3701-15-03 that reflect current CDC and American Thoracic Society standards of care.

11. 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?

As required by R.C. 339.73 and R.C. 3701.146, Ohio uses the testing and treatment guidelines set forth by CDC or ATS. The CDC guidelines have been endorsed and adopted by ATS so that there is only one national standard for Ohio adopt.

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.

12. 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.

13. 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.

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

Pursuant to R.C. 3701.13, ODH shall have supervision of all matters relating to the preservation of the life and health of the people, including the control and suppression of infectious disease in humans, including TB. No other state agency has this authority.

15. 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.

Per Ohio Administrative Code 3701-3-02, tuberculosis is a Class B disease that must be reported by the end of the next business day. Mandatory reporters are encouraged to report TB through the statewide disease surveillance system. ODH reviews TB case data in the electronic disease surveillance system for compliance.

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

CSIPublicComments@governor.ohio.gov

Adverse Impact to Business

16. 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; and**
- b. Identify the nature of all adverse impact (e.g., 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 TB Control Units are already complying with tuberculosis standards established in R.C. 339.71 through 339.89. Their work will not change with the proposed rule change in rule 3701-15-03. The minor change includes new medical guidance released by CDC and ATS in 2018 and 2019.

17. 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 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

18. 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.

19. 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.

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

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

CSIPublicComments@governor.ohio.gov

ODH provides technical assistance to local TB Control Units and providers by telephone and email. 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.

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

CSIPublicComments@governor.ohio.gov