

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Department of Health

Regulation/Package Title: Chapter 3701-17, Residential Care Facilities

Rule Number(s): 3701-17-55, 3701-17-58, 3701-17-62

Date: June 9, 2014

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☐ Rescinded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.

In response to stakeholder concerns regarding the recurrent shortage of tuberculin skin tests, ODH is proposing amendments to rules 3701-17-55, 3701-17-58, and 3701-17-62 of the Administrative Code to generally reduce the frequency of required tuberculosis ("TB") testing.

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Recommended changes to the TB testing regulations for residential care facilities (“RCFs”) will decrease costs to the facility, and relieve the administrative burden of record keeping for health care workers in counties where TB morbidity is low and annual testing has not identified previously unknown disease. Further, assessment for TB symptoms will be conducted annually. Requested changes are consistent with guidelines published by the Centers for Disease Control and Prevention, and meet standards of the ODH, TB Prevention and Control Program. ODH does not believe there will be a negative impact to the public’s health, or the health of residents or RCF employees.

ODH has drafted amendments to the following rules:

- 3701-17-55: This rule sets forth the qualifications for personnel working in residential care facilities.

The rule has been amended to remove specific tuberculosis testing requirements staff; facilities will now provide for tuberculosis testing to staff in accordance with the tuberculosis control plan developed in accordance with the home’s assessment required under draft rule 3701-17-62.

- 3701-17-58: This rule details the requirements for resident medical assessments.

The rule has been amended to remove specific tuberculosis testing requirements for facility residents; facilities will now provide for tuberculosis testing of residents in accordance with the tuberculosis control plan developed in accordance with the home’s assessment required under draft rule 3701-17-62.

- 3701-17-62: This rule requires residential care facilities to have and follow infection control procedures that limit the likelihood of transmission of disease.

This rule has been amended to require each facility to develop a tuberculosis control plan in accordance with the most recent guidance issued by the United States Centers for Disease Control and Prevention and to retain documentation of compliance.

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

3721.04

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.

No.

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

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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)?**

These rules to prevent the transmission of disease in a population that is susceptible to TB.

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

Successful outcomes are measured through a standard survey (inspection) process. This process is generally conducted once every fifteen months. Successful outcomes would be indicated by a finding of compliance with the proposed rule requirements. Further evidence of success would be represented by the number of complaints received and the number of validated complaint surveys.

Development of the Regulation

- 7. 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.

ODH met with a stakeholder regarding the tuberculin skin test shortage. As a result of this meeting, ODH agreed to modify the rules to require tuberculosis testing in accordance with the facility's assessment under CDC guidelines. The draft rule reflects ODH's commitments at that meeting.

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

See response to #7, above.

- 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?**

United States Centers for Disease Control and Prevention's "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Settings, 2005," MMWR 2005, Volume 54, No. RR-17, available online at: <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>.

- 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?**

ODH did not consider any alternatives to the proposed regulation.

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.

A performance based regulation was not deemed appropriate for this standard and not authorized by statute.

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

The agency conducted a thorough review of the Ohio Revised Code and Ohio Administrative Code to ensure there are no other regulations in place regarding personnel requirements in nursing homes.

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.

An on-site survey may be initiated to determine compliance with this rule. The survey will be done by health care facility program staff using a standard survey tool. This staff will have been trained in the survey process, including understanding of the regulation.

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;

The impacted business community consists of licensed residential care facilities. As of January 10, 2014 there are 615 licensed residential care facilities in Ohio.

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

The adverse impact of these rules includes staff time associated with conducting an assessment and developing a tuberculosis control plan for the home.

It should be noted that even though not required by rule, most if not all facilities currently conduct a facility assessment consistent with the CDC Guidelines.

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

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“representative business.” Please include the source for your information/estimated impact.

- Performing TB assessment of the facility

ODH estimates this would require up to 4 hours of staff time:

Registered Nurse

- \$28.85 per hour

Additionally, it should be noted that the proposed change removes specific annual testing requirements. As a result of allowing facilities to conduct assessments consistent with CDC Guidelines, ODH believes many facilities in Ohio would become a “low risk” facility and would significantly reduce the number of TB tests administered to staff and residents each year, thus eliminating costs associated with those tests. Some facilities may have a higher risk assessment and be subject to annual testing.

*All figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2012, using the codes for Registered Nurses (29-1141).

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

Section 3721.04 requires ODH to establish rules for residential care facilities. These amendments establish requirements as they relate to TB testing.

Regulatory Flexibility

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

Alternative means of compliance may be achieved through a variance. Variances may be granted for any of the requirements of this Chapter if the Director determines: that the requirement has been met in an alternative manner, that the strict application of the requirement would result in undue hardship, and that the granting of the waiver or variance would not jeopardize the health or safety of the public. The requirements for a variance are set forth in rule 3701-17-26 and are determined on a case-by-case basis.

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 is committed to the goal of ensuring that regulated customers have the opportunity to achieve compliance with ODH's procedural requirements. Therefore, when it is both feasible and appropriate,

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ODH will provide one (1) warning letter to a regulated customer who commits a first time or isolated violation of a "minor" paperwork or procedural requirement, such as failing to submit a timely and complete license renewal application or other required documentation to ODH. ODH will not impose a civil monetary penalty for such a violation, and will give the customer a reasonable amount of time to correct the violation, unless:

1. the violation constitutes a failure to comply with federal laws or regulations enforced by ODH, and the penalty is mandated by federal law;
 2. the Director of Health or one of his designees has determined that the violation poses an actual or potential threat to the health, safety, or welfare of the general public;
 3. the violation involves knowing or willful conduct that may result in conviction for a felony;
 4. failure to impose the penalty would impede or interfere with the detection of criminal activity;
- or
5. the violation pertains to the assessment or collection of any monies owed to the state.

This Policy Statement should not be construed as a waiver of ODH's authority to enforce any law or regulation requiring a person or entity to obtain a valid permit or license before engaging in regulated activity, or enforce any other state or federal law.

This policy is available online at:

<http://www.odh.ohio.gov/rules/ombudsman/regulatoryombudsman.aspx>.

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

The agency maintains program staff that can assist and provide guidance to licensee to improve their survey outcomes and maintain compliance through the Bureau Long Term Care Quality:

<http://www.odh.ohio.gov/odhprograms/ltc/nurhome/nurhome1.aspx>.