ACTION: Original

Rule Summary and Fiscal Analysis Part A - General Questions

Rule Number: 3701-15-03

Rule Type: Amendment

Rule Title/Tagline: Tuberculosis standards for the purposes of section 3701.14 of the

Revised Code.

Agency Name: Department of Health

Division:

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I. Rule Summary

- 1. Is this a five year rule review? Yes
 - A. What is the rule's five year review date? 1/5/2018
- 2. Is this rule the result of recent legislation? No
- 3. What statute is this rule being promulgated under? 119.03
- 4. What statute(s) grant rule writing authority? 3701.146
- 5. What statute(s) does the rule implement or amplify? 339.71, 339.72, 3701.14
- 6. What are the reasons for proposing the rule?

This amended rule is proposed to satisfy the five-year review requirement and to align with national tuberculosis standards of care.

7. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.

For purposes of section 3701.14 of the Revised Code, this rule adopts, by reference, tuberculosis standards of care. The rule is amended to update tuberculosis standards of care and provides updated references based on current information and guidance

Page 2 Rule Number: **3701-15-03**

from the Centers for Disease Control and Prevention, American Thoracic Society, and Infectious Diseases Society of America.

- 8. Does the rule incorporate material by reference? Yes
- 9. If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.71 to 121.76, please explain the basis for the exemption and how an individual can find the referenced material.

This rule references the Ohio Revised Code which is exempt from inclusion in this filing, pursuant to R.C. 121.76(A)(1). Also adopted by reference are the following tuberculosis standards of care as provided by the Centers for Disease Control and Prevention (CDC), the American Thoracic Society, and the Infectious Disease Society of America:

- 1. "Core Curriculum on Tuberculosis; What Every Clinician Should Know." https://www.cdc.gov/tb/education/corecurr/index.htm#Anchor Interactive.
- 2. "Treatment of Drug-Susceptible Tuberculosis," "Clinical Infectious Disease," 2016; 63(7):e 147-95. https://www.ncbi.nlm.nih.gov/pubmed/27516382 and https://academic.oup.com/cid/article-lookup/doi/10.1093/cid/ciw376
- 3. "Recommendations for Use of an Isoniazid-Rifapentine Regimen with Direct Observation to Treat Latent Mycobacterium tuberculosis Infection." and
- 4. "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Setting," 2005 "Morbidity and Mortality Weekly Report: December 30, 2005/54(RR17); 1-141." https://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

These adopted industry standards of care are exempt from inclusion in this filing pursuant to R.C. 121.75(E) and are readily available free-of-charge via the links provided. ODH has placed links to the adopted tuberculosis standards of care on its website: http://www.odh.ohio.gov/rules/refmat/refmat.aspx.

10. If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.

Not Applicable

II. Fiscal Analysis

11. As a result of this proposed rule, please estimate the increase / decrease in revenues or expenditures affecting this agency, or the state generally, in the current biennium or future years. If the proposed rule is likely to have a different fiscal effect in future years, please describe the expected difference and operation.

This will have no impact on revenues or expenditures.

Page 3 Rule Number: **3701-15-03**

\$0.00

Not applicable

12. What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?

Tuberculosis standards of care have been updated. Existing costs of compliance should not change.

- 13. Does the rule increase local government costs? (If yes, you must complete an RSFA Part B). No
- 14. Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C). No

III. Common Sense Initiative (CSI) Questions

- 15. Was this rule filed with the Common Sense Initiative Office? Yes
- 16. Does this rule have an adverse impact on business? No
 - A. Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business? No
 - B. Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms? No
 - C. Does this rule require specific expenditures or the report of information as a condition of compliance? Yes

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