Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes¹ \boxtimes Not Needed \square

If/when this economic impact analysis (EIA) is published in the Virginia Register of Regulations, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).



Virginia Department of Planning and Budget **Economic Impact Analysis**

12 VAC 5-90 Regulations for Disease Reporting and Control Virginia Department of Health Town Hall Action/Stage: 5208 / 8504

February 26, 2019

Summary of the Proposed Amendments to Regulation

The State Board of Health (Board) proposes to: 1) reduce the required time within which laboratories must submit specimens to the Division of Consolidated Laboratory Services when specified diseases are detected, 2) amend the frequency of influenza reporting, 3) require laboratories to submit results of tests for tuberculosis infection, 4) change the required method of reporting morbidity (electronic rather than paper), 5) eliminate redundant reporting, 6) amend one of the criteria for testing a child's blood level, and 7) make several clarifying amendments.

Result of Analysis

Some of the proposed amendments are moderately more burdensome for regulated entities, but enable the Virginia Department of Health (VDH) to more quickly be aware of disease outbreaks and to take appropriate action. Other proposed amendments unambiguously produce net benefit.

Estimated Economic Impact

Under the current regulation, when a laboratory identifies evidence of any of numerous conditions listed in the regulation, it must submit the initial isolate (preferred) or other initial specimen to the Division of Consolidated Laboratory Services within seven days of

¹ Adverse impact is indicated if there is any increase in cost for any entity, even if the benefits exceed the costs.

identification. The Board proposes to instead require that the initial isolate be submitted within **five days** or the clinical specimen within **two days** of a positive result.

Under the current regulation, each individual case of influenza does not need to be reported to VDH (only the number of cases). Under the proposed regulation, each individual confirmed case of influenza would need to be reported to VDH.

The Board also proposes to newly require that laboratories submit results of tests for tuberculosis infection. VDH does not believe that this will require significant additional staff time. As the majority of major hospital systems and commercial labs in Virginia report to VDH electronically, these systems would need to update their algorithm to include results of tests for tuberculosis infection in the reports that they send.

These three proposed changes are moderately more burdensome for regulated entities, but enable VDH to more quickly be aware of disease outbreaks and to take appropriate action.

The Board proposes to change the required method of reporting morbidity from paper to electronic. According to VDH, the time required to complete a report through their electronic portal is comparable to that required to complete the paper form. Reporters are able to save time and money as entering into the portal removes the need to mail the paper form.

The current regulation requires that laboratory directors report any laboratory examination of any clinical specimen, whether performed in-house or referred to a reference laboratory, which yields evidence, by the laboratory method(s) indicated or any other confirmatory test, of diseases specified in the regulation. The Board proposes to no longer require that the director of the laboratory of origin report to VDH if the laboratory director ascertains that the reference laboratory that tests a specimen reports to VDH electronically. This would save staff time for the laboratory of origin, and have no negative impact.

The Regulations for Disease Reporting and Control state that every child shall be tested to determine the blood lead level at 12 months and 24 months of age if the health care provider determines that the child meets any of the criteria listed in the regulation. Additionally, children 25 months through 72 months of age who present for medical care and meet any of the specified criteria shall also be tested if they have either not previously been tested for blood lead level or were previously tested but experienced a change since testing that has resulted in an increased

risk of lead exposure. One of the criteria under the current regulation is "The child is living in or regularly visiting a house, apartment, dwelling, structure, or child care facility built before 1960." The Board proposes to replace "1960" with "1950." According to VDH, this change is based upon the U.S. Centers for Disease Control and Prevention's determination that it is the homes built before 1950 that have high lead risk.

Businesses and Entities Affected

The proposed amendments affect laboratories, physician offices, hospitals, nursing homes, assisted living facilities and correctional facilities, as well as the directors of these facilities, physicians, and administrative staff. VDH estimates that 20,000 physicians, 125 laboratories, 100 hospitals, and 250 nursing homes are affected. To the extent that the proposed amendments improve public health, all citizens of the Commonwealth are potentially affected.

Localities Particularly Affected

The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment

The proposed amendments are unlikely to significantly affect total employment.

Effects on the Use and' Value of Private Property

The proposed amendments are unlikely to significantly affect the use and value of private property.

Real Estate Development Costs

The proposed amendments do not affect real estate development costs.

Small Businesses:

Definition

Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

Costs and Other Effects

The proposals to reduce the required time within which laboratories must submit specimens, and to newly require that laboratories submit results of tests for tuberculosis

infection, would moderately increase costs for small labs. The proposal to require that each individual confirmed case of influenza be reported would moderately increase costs for small physician offices and other medical facilities.

Alternative Method that Minimizes Adverse Impact

There are no clear alternative methods that both reduce adverse impact and meet the intended policy goals.

Adverse Impacts:

Businesses:

The proposals to reduce the required time within which laboratories must submit specimens, and to newly require that laboratories submit results of tests for tuberculosis infection, would moderately increase costs for labs. The proposal to require that each individual confirmed case of influenza be reported would moderately increase costs for physician offices and other medical facilities.

Localities:

The proposed amendments do not adversely affect localities.

Other Entities:

The proposed amendments do not adversely affect other entities.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5)the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(C): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on

affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.