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): Yes[1] ☒ Not Needed ☐

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 / 8637
July 15, 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.

Background

The *Regulations for Disease Reporting and Control* provide information about the process and procedures for reporting diseases to the Virginia Department of Health (VDH), including what diseases must be reported, who must report them and other details related to reporting and disease control.

Estimated Benefits and Costs

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

[1] Adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined.

specimen to the Division of Consolidated Laboratory Services within **seven days** of 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 Other Entities Affected

The proposed amendments potentially affect the 654 medical laboratories, 4,471 physician offices, 188 hospitals, 291 nursing homes, 184 assisted living facilities, and correctional facilities in Virginia, as well as the directors of these facilities, physicians, and administrative staff.[2] To the extent that the proposed amendments improve public health, all citizens of the Commonwealth are potentially affected.

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. The proposal to change the required method of reporting morbidity from paper to electronic would save reporting entities time and money as entering into the portal removes the need to mail the paper form. The proposal 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 would save staff time for the laboratory of origin.

Localities[3] Affected[4]

The proposed amendments potentially affect all localities, and are not known to disproportionally affect particular localities. To the extent that some of the affected entities may be associated with local governments, the proposed amendments that affect costs, either positively or negatively as described above, would affect local governments.

[2] Data source: Virginia Employment Commission

[3] "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

[4] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

Projected Impact on Employment

The proposed amendments do not appear to substantially affect total employment.

Effects on the Use and Value of Private Property

The proposed amendments do not substantially affect the use and value of private property. The proposed amendments do not affect real estate development costs.

Adverse Effect on Small Businesses[5]:

Types and Estimated Number of Small Businesses Affected

The proposed amendments potentially affect the 651 small medical laboratories, 4,466 small physician offices, 134 small hospitals, 290 small nursing homes, 180 small assisted living facilities, and correctional facilities in the Commonwealth, as well as the directors of these facilities, physicians, and administrative staff.[6]

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 small 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.

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.

[5] 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."

[6] Data source: Virginia Employment Commission

Adverse impacts: Pursuant to Code § 2.2-4007.04(D): 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.