



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 / 9515** February 23, 2022

The Department of Planning and Budget (DPB) 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). The analysis presented below represents DPB's best estimate of these economic impacts.¹

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) require that every confirmed individual case of influenza with individual-specific details be reported rather than just the total number of confirmed cases, 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, 7) add ethnicity to the categories of personal information to be reported, and 8) 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),

¹ Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis 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.

including what diseases must be reported, who must report them, and other details related to reporting and disease control.

Estimated Benefits and Costs

Four of the proposed changes would add additional burden for regulated entities, but would also enable VDH to be better informed and/or more quickly be aware of disease outbreaks and to take appropriate action. Three other changes would reduce burden for affected entities.

Changes that Would Add Burden

Under the current regulation, when a laboratory identifies evidence of any of the 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 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, for influenza reporting, physicians and persons in charge of medical care facilities (hospitals or nursing homes) only need to report to the local health department the total number of confirmed cases (and type of influenza, if available). Under the proposed regulation, each individual confirmed case of influenza with individual specific information would need to be reported to the local health department. This proposed change would affect physician offices, but may not substantively affect most medical care facilities due to the existence of a variance.² Pursuant to the variance, persons in charge of medical care facilities would be exempt from reporting most cases of influenza when such person has written documentation that those reports are being made by the director of the laboratory operating in the same facility. Such laboratory directors are separately required by this regulation to make such reports.

The current regulation requires that for: a) physicians who treat or examine any person who is suffering from or who is suspected of having a reportable disease or condition, b) laboratory directors whose laboratory examination of any clinical specimen yields evidence of a reportable disease, and c) persons in charge of a medical care facility upon the occurrence in or admission to the facility of a patient with a reportable disease, that the patient's name, address,

² See https://www.vdh.virginia.gov/content/uploads/sites/13/2019/04/MedicalFacilityDirector_Exemption_Letter.pdf

age, date of birth, race, sex, and pregnancy status for females be reported to the local health department. The Board proposes to add ethnicity to the list of required fields.

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, because the majority of major hospital systems and commercial labs in Virginia report these results to VDH electronically. To comply with the proposed changes, these systems would need to update their algorithm to include results of tests for tuberculosis infection in the reports that they send.

Changes that Would Reduce Burden

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 an outside 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 outside 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. This would reduce the required amount of testing.

Businesses and Other Entities Affected

The proposed amendments potentially affect the 667 medical laboratories, 4,647 physician offices, 190 hospitals, 298 nursing homes, 192 assisted living facilities, and correctional facilities in Virginia, as well as the directors of these facilities, physicians, and administrative staff.³ To the extent that the proposed amendments improve public health, all citizens of the Commonwealth are potentially affected.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.⁴ An 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. For at least some laboratories, the costs in staff time associated with the proposed reduction in the number of days within which the labs must send specimens to the Division of Consolidated Laboratory Services, and the proposed new requirement that laboratories submit results of tests for tuberculosis infection, likely outweigh the potential benefits of other proposed amendments. For example, as described in the Estimated Benefits and Costs section, when laboratories use outside reference labs the laboratory of origin would no longer be required to report to VDH if the outside reference laboratory already reports the relevant data to VDH electronically. The savings in reduced reporting time only apply when using an outside reference laboratory that already reports to VDH. Laboratories that do not often use outside reference labs would see little reduction in costs from this proposal.

Also, for at least some physician offices, the costs in staff time associated with newly requiring that each individual confirmed case of influenza with individual specific information

³ Data source: Virginia Employment Commission

⁴ 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. Statute does not define "adverse impact," state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.

be reported likely outweigh the potential benefits of other proposed amendments. Thus, an adverse impact is indicated.

Small Businesses⁵ Affected:⁶

Types and Estimated Number of Small Businesses Affected

The proposed amendments potentially affect the 665 small medical laboratories, 4,637 small physician offices, 135 small hospitals, 297 small nursing homes, and 188 small assisted living facilities in the Commonwealth, as well as the directors of these facilities, physicians, and administrative staff.⁷

Costs and Other Effects

All of the costs and other effects described above in the Estimated Benefits and Costs section apply to the entities that qualify as small businesses.

Alternative Method that Minimizes Adverse Impact

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

Localities⁸ Affected⁹

The proposed amendments potentially affect all localities, and are not known to disproportionately 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.

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 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.

⁷ Data source: Virginia Employment Commission

⁸ “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.

⁹ § 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

As indicated in the Estimated Benefits and Costs section, some of the proposed changes would increase costs for affected entities, mostly through required staff time, while other proposed changes would reduce costs. This would affect the use and value of those affected entities that are private businesses, but the impact would not likely be large in net. The proposed amendments do not affect real estate development costs.