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: 5581/9399
October 8, 2021

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 make permanent a discretionary emergency regulation that would add COVID-19 to the list of reportable diseases.[2] Specifically, the proposed amendments would (i) specify the patient information to be collected and reported to the Virginia Department of Health (VDH), (ii) require COVID-19 case and laboratory reports to be submitted electronically, (iii) identify all entities (physicians, lab directors, and other non-traditional providers who conduct COVID testing) that are required to report COVID-19, and (iv) add "coronavirus, severe" to the list of infectious diseases that shall be reported to persons practicing funeral services at the time of transferring custody of a dead body.

[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.

[2] See https://townhall.virginia.gov/l/ViewStage.cfm?stageid=9040 for the Emergency/NOIRA stage, which became effective on January 20, 2021 and expires on July 19, 2022.

Background

The *Regulations for Disease Reporting and Control* provide information about the process and procedures for reporting diseases to VDH, including what diseases must be reported, who must report them, and other details.

The 2020 federal Coronavirus Aid, Relief, and Economic Security (CARES) Act requires that every laboratory that performs a test that is "intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 shall report the results of each such test to the Secretary of Health and Human Services… until the end of the Public Health Emergency declaration with respect to COVID-19 or any extension of such declaration."[3] Details regarding who had to report testing data to whom, and what information had to be reported, were left to the Secretary's discretion. A federal public health emergency for COVID-19 was first declared on January 31, 2020 and has been renewed every three months since then, most recently on October 18, 2021.[4]

In order to implement these requirements, the Centers for Disease Prevention and Control (CDC) has communicated specific requirements for laboratories, including details regarding who must make reports (what entities are considered "laboratories") and what data elements must be reported.[5] The CDC requires all COVID-19 testing sites to have a Clinical Laboratory Improvement Amendments (CLIA) certificate and requires every CLIA-certified testing site to report data for all diagnostic and screening testing completed, including molecular, antigen, and antibody testing for each individual tested, within 24 hours of test completion.[6] These reporting requirements apply to all entities conducting COVID-19 testing; VDH's reporting requirements described below separate reporters into two groups for the purposes of this regulation: (a) physicians and directors of medical care facilities, and (b) directors of laboratories, including

[3] See https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf, Sec. 18115(a). The Act became effective March 27, 2020.
[4] See https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx. As of this writing, there is no indication as to when the emergency declaration will stop being renewed.
[5] See https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html.
[6] See https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/cliabrochure.pdf. Anyone who performs testing of human specimens for the diagnosis, prevention or treatment of disease or health problems must apply for a CLIA certificate. This includes physicians who operate their own in-office laboratories and medical care facilities. There are 4 types of CLIA certificates: Certificate of Waiver, Provider Performed Microscopy, Compliance, and Accreditation. CLIA Certificate of Waiver holders may now include various entities that have started conducting some types of COVID tests, such as school districts, employers, sports teams, etc. Thus, "labs" and "directors of laboratories" are broad classifications in the context of CARES Act reporting requirements and this regulation.

other entities that hold CLIA Certificates of Waiver. The CDC has also directed all entities conducting COVID-19 testing to report testing data to state or local public health departments according to state law or policy.

Subsequently, the Board promulgated emergency regulations to clarify and enforce the CARES Act reporting requirements and to collect necessary information to guide state-level policy making in response to COVID-19.[7] Specifically, the Board added "Coronavirus, severe" to 12 VAC 5-90-80 *List of diseases that shall be reported* and a subsection specifying who would report COVID-19 tests and how. The proposed amendments at this stage largely preserve the changes made at the emergency stage, with the exception of one significant change that is discussed below.

The proposed amendments require physicians and directors of medical care facilities to report COVID-19 testing data when a person who is infected with or is suspected of having COVID-19 is treated or examined, hospitalized, or admitted to an intensive care unit. Physicians and directors of medical care facilities would be required to report "the person's name, telephone number, email address, address, age, date of birth, race, ethnicity, sex, and pregnancy status; name of disease diagnosed or suspected; the medical record number (if applicable); the date of onset of illness; available laboratory tests and results; and the name, address, and telephone number of the physician and medical facility where the examination was made."[8] The proposed language also specifies that case reports shall be submitted immediately or within 24 hours by entering the information into VDH's online Confidential Morbidity Report portal or via electronic case reporting.[9]

The proposed amendments include analogous reporting requirements for directors of laboratories, including other entities that hold CLIA Certificates of Waiver; while the patient

[7] See https://townhall.virginia.gov/l/ViewStage.cfm?stageid=9040. Although the emergency regulation became effective January 20, 2021, VDH reported that they had begun collecting COVID-19 data in March 2020, as required by the CARES Act. The emergency regulation expires on July 19, 2022.

[8] Details regarding data elements appear in a new section 80-90 I., titled COVID-19 (SARS-CoV-2), to specify that they are only required for COVID-19. VDH has clarified that physicians would not be required to report patients' other diagnosed or suspected health conditions, nor be required to submit information on any lab tests that are not COVID-19 tests.

[9] The proposed amendments include hyperlinks to these online portals. The emergency language requires physicians and directors of medical care facilities to report hospitalizations and intensive care unit admissions through the Emergency Department Care Coordination program. That requirement would be removed at this stage. Separately, VDH also created a point-of-care reporting portal in September 2020 due to the high volume of point-of-care tests

data to be reported is the same as above, labs would also have to report the source of the specimen, the laboratory method and the result. Under the emergency regulation, lab directors were required to report both *positive and negative* test results; as per the proposed amendments at this stage, lab directors would only have to report *positive* test results. In practice, this change would only affect lab directors once the federal public health emergency declaration is lifted, since the CARES Act requires that *every* test be reported to the Secretary of Health and Human Services and VDH will continue to act as a conduit for that information. As for physicians, lab directors would also be required to report tests within 24 hours, either by entering information into VDH's online portals for lab reporting or via electronic lab reporting.[10]

Lastly, 12 VAC 5-90-90 states that, "In accordance with § 32.1-37.1 of the Code of Virginia, any person in charge of a hospital, nursing facility or nursing home, assisted living facility, or correctional facility shall, at the time of transferring custody of any dead body to any person practicing funeral services, notify the person practicing funeral services or his agent if the dead person was known to have had, immediately prior to death, an infectious disease which may be transmitted through exposure to any bodily fluids." COVID-19 was added to the list of infectious diseases subject to this requirement at the emergency stage; this change would be made permanent.

Estimated Benefits and Costs[11]

The primary benefits of timely data collection about COVID-19 suspected cases and test results were and continue to be the protection of public health. In the initial stages of the COVID-19 pandemic, this included critical decision making regarding the procurement of personal protective equipment for hospital staff and other frontline workers, the procurement and allocation of ventilators and oxygen and other critical supplies, and hiring and staffing decisions for hospitals, nursing homes, emergency rooms, and other providers. Funeral services workers

that were being conducted for COVID-19 to make reporting easier. (https://apps.vdh.virginia.gov/pocreporting/login/login.aspx)

[10] This deviates from the emergency stage, which allowed the use of paper Epi-1 forms or the laboratory's own forms if it contained the required information, and computer generated reports containing the required information.

[11] The Economic Impact Analysis compares the proposed regulation to the regulation in the Virginia Administrative Code. The emergency regulation is: 1) not in the Virginia Administrative Code (see http://law.lis.virginia.gov/admincode) and 2) temporary. Thus, the Economic Impact Analysis assesses the impact of changing the permanent regulations. Consequently, to the extent that the proposed text matches the emergency text, some of the benefits and costs described here have likely already accrued.

would benefit from the addition of COVID-19 to the list of infectious diseases they are informed of so that they can take adequate precautions.

In addition, collecting information on both positive and negative tests allowed public health experts to calculate and report the percent-positivity rate, which served as a leading indicator of community transmission at the local, regional, and state levels. This information was and continues to be used to guide public health policies such as social distancing, recommendations (and mandates) regarding masking, travel, capacity limits for various businesses, and lockdowns. Thus, in addition to meeting federal requirements, the proposed amendments have benefited and would likely continue to benefit the public, at least as long as the pandemic continues.

The direct costs of the proposed amendments fall on physicians and lab directors who face a significant reporting burden and a binding time constraint. To the extent that this reporting is required by the CARES Act and the Secretary of Health and Human Services, these costs are unavoidable. VDH has attempted to mitigate this burden by providing multiple online portals and secure electronic transmission methods in order to reduce the time and paperwork costs of these requirements. As the pandemic has evolved, the criteria for testing have changed and tests have become more widely available; people may be more likely to get tested in order to travel or attend an event, or to get tested more frequently if they have to be present in-person for work or education. Thus, as the number of negative tests increase in general, percent positivity may not be as informative or useful as it once was. In recognition of these trends, the Board proposes to remove the requirement to report negative COVID-19 tests, which would significantly reduce the reporting burden for labs, including entities with CLIA waivers. At the same time, requiring that positive cases and tests be reported would ensure that new "spikes" or "hotspots" can be identified quickly.

Many of the patient-specific data elements (such as biographical and contact information) that would be required by these proposed changes are already required for other reportable diseases. However, this proposed change is the first time that this regulation has required that the telephone number, email address, and ethnicity be reported. An indirect cost of the proposed amendments, therefore, relates to individuals' data privacy and the risk that one's personal biographical details, contact details, and health information may be accessed by unauthorized

persons or entities and/or used for nefarious purposes. Such concerns may discourage individuals from getting tested even when they do exhibit symptoms, which would defeat the purpose of collecting this information. All the patient-related data fields included in the proposed amendments (except e-mail address) are currently required by the CARES Act, so VDH does not have much leeway in amending the scope of data collected.[12] Further, the reported data are transmitted to the CDC and possibly other entities, which amplifies privacy concerns since data sharing increases the risk of a security breach, even if the data are de-identified.

In order to ameliorate these costs in the long run, the Board and VDH could revisit the scope of data collection and the list of data fields once the federal public health emergency is lifted and re-evaluate the proposed requirements. If COVID-19 ends up becoming more common and less dangerous, VDH could consider only requiring physicians to report cases that require hospitalization or admission to intensive care, or only requiring lab reports to include select demographic data but no personally identifiable information.

Businesses and Other Entities Affected

The proposed amendments affect roughly 20,000 physicians, 125 laboratories, 100 hospitals, and 250 nursing homes in Virginia.[13] There are currently 7,791 entities with CLIA certificates in Virginia (including the 125 laboratories mentioned previously) who are potentially impacted by the proposed amendments.[14] Some of these entities may operate multiple testing locations, such as a school district with one certificate that covers 13 schools.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.[15] An adverse impact is indicated if there is any increase in net cost or

[12] See https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf from https://www.hhs.gov/coronavirus/testing/covid-19-diagnostic-data-reporting/index.html. The list of data fields on pages 2-4 contains all the data fields required by VDH in the proposed text, except the patient's email address. Individuals may choose not to disclose biographical or contact information when getting tested. Although testing sites are required to make every effort to collect this information, if individuals choose not to disclose certain information the testing site would still be able to submit incomplete records to VDH.

[13] Agency Background Document, page 5: https://townhall.virginia.gov/l/GetFile.cfm?File=58\5581\9399\AgencyStatement_VDH_9399_v1.pdf.

[14] VDH reported that in federal fiscal years 2020 and 2021, 1,429 new CLIA Certificates of Waiver were created for testing entities in Virginia. Not all of these were testing for COVID-19, but a large majority were. Further, there is no federal requirement for facilities with CLIA certificates to notify VDH or CLIA if they have added a test as long as the test of the same complexity and specialty of their certificate; thus all 7,791 entities with current certificates may be affected.

[15] 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

reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. As noted above, the proposal to add new reporting requirements would increase costs for physicians, hospitals, nursing homes, labs and other testing centers. Thus, an adverse impact is indicated.

Small Businesses[16] Affected:[17]

To the extent that some of the affected laboratories or nursing homes may be small businesses, the proposed amendments would appear to adversely affect small businesses.

Types and Estimated Number of Small Businesses Affected

The number of small businesses impacted by the proposed amendments is unknown. Some of the affected laboratories or nursing homes may be small businesses and some small businesses (not necessarily connected to healthcare) may have acquired CLIA Waivers to offer on-site testing for employees or clients. To the extent that offering testing improves employee or client satisfaction for the latter category of small businesses, their costs may be offset by other gains.

Costs and Other Effects

The proposed amendments increase reporting requirements, which requires staff time. An adverse economic impact[18] on laboratories, including entities with CLIA Waivers is indicated because there do not appear to be any offsetting direct benefits to these small businesses.

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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.

[16] 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."

[17] 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.

[18] 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.

Alternative Method that Minimizes Adverse Impact

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

Localities[19] Affected[20]

The proposed amendments potentially affect all 132 localities, but localities with greater COVID-19 prevalence may have higher rates of testing; thus, physicians, hospitals, nursing homes, and labs in those localities would be disproportionately affected. The proposed amendments do not introduce costs for local governments. Accordingly, no additional funds would be required. Consequently, no adverse economic impact[21] is indicated for any particular locality.

Projected Impact on Employment

The proposed amendments do not appear to affect total employment directly. Some hospitals, nursing homes, or labs may have hired additional temporary staff in order to meet the reporting requirements.

Effects on the Use and Value of Private Property

The proposed new reporting requirements for private hospitals, nursing homes, and laboratories, including entities with CLIA waivers moderately increase their costs. However, given the role played by such organizations in responding to the COVID-19 pandemic and the public health benefits of the data collected, it would be unlikely to reduce the value of these firms. Some laboratories may have expanded the scale of their operations and become more valuable if they were able to hire personnel and use technology to more efficiently meet the reporting requirements while also performing more tests. The proposed amendments do not affect real estate development costs.

[19] "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.

[20] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

[21] 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.