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Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-90
VAC Chapter title(s)	Disease Reporting and Control Regulations
Action title	COVID-19 Emergency Update
Date this document prepared	July 1, 2021

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

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. VDH is proposing an amendment to the regulations to ensure all health providers report necessary public health information.

This regulatory action requires COVID-19 case and laboratory report forms be submitted electronically; clarifies that the category “laboratory directors” includes any entity that holds CLIA Certificates of Waiver; adds ethnicity to the fields required to be reported by all parties related to COVID-19; and adds “coronavirus, severe” to the list of infectious disease that shall be reported to persons practicing funeral services.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

No acronyms are used that are not defined in context.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Emergency amendments to these regulations became effective on January 20, 2021. Those emergency amendments are set to expire on July 19, 2022. The impetus for this regulatory action is to make several of those amendments permanent. The proposed changes are essential to protect the health and safety of citizens because they will improve the ability of VDH to conduct surveillance and investigations, including collection of necessary public health information. Further, the proposed changes are essential to continue to implement disease control measures for COVID-19. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Chapter 2 of Title 32.1 of the Code of Virginia, §§ 32.1-12 and 32.1-35 through 32.1-73, contain mandatory language authorizing the State Board of Health to promulgate the proposed regulations.

Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth are to be reportable and the method by which they are to be reported.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The proposed changes are essential to protect the health and safety of citizens because they will improve the ability of VDH to conduct surveillance and investigations, collect necessary public health information,

and continue to implement disease control measures for COVID-19. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

Amendments to current regulations will:

- For COVID-19 specifically:
  - Require all suspect or confirmed COVID-19 case report forms be submitted electronically to VDH;
  - Clarify that the category "laboratory directors" includes all entities that hold CLIA Certificates of Waiver so that entities testing for COVID-19 are required to report to VDH;
  - Require all COVID-19 laboratory reports be submitted electronically to VDH;
  - Add the requirement that patient phone number, email address, and ethnicity be included in the list of fields that are reported by physicians, laboratory directors, and directors of medical care facilities.
  - Add "coronavirus, severe" to the list of infectious diseases that shall be reported to persons practicing funeral services.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

The primary advantages to the public are the improved ability of the agency to control the risk of disease in the community based on timelier reporting through VDHs online morbidity reporting portal and the improved ability to accurately report COVID-19 data. No disadvantages have been identified.

The primary advantage to the agency is that the proposed changes improve the focus of surveillance and ability of VDH to conduct surveillance and implement disease control for conditions of public health concern in a timely manner. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public. No disadvantages have been identified.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act is the applicable federal law related to COVID-19 reporting. None of the changes in this document would make this regulation more restrictive than requirements specified in the CARES Act.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

No particular agency is affected by these amendments.

Localities Particularly Affected

No particular locality is affected by these amendments.

Other Entities Particularly Affected

Persons responsible for reporting, particularly laboratories, and persons in charge of funeral homes are particularly affected by these amendments.

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	Potential non-general fund cost savings for VDH are expected with the elimination of COVID-19 paper reports.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	No economic impacts expected.
For all agencies: Benefits the regulatory change is designed to produce.	More efficient and accurate reporting of data by the VDH.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	No economic impacts expected.

Benefits the regulatory change is designed to produce.	More efficient and accurate reporting of data by the VDH.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	This regulatory change impacts persons who are required to report (i.e. physicians, medical directories, laboratories, and persons with COVID-19 related CLIA waivers).
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	20,000 physicians 125 laboratories 100 hospitals 250 nursing homes Some of these may be small businesses.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	No additional costs are expected based on changes proposed to the existing regulations.
Benefits the regulatory change is designed to produce.	Benefits include more timely and complete reporting of COVID-19 to VDH so that actions can be taken to minimize the spread of disease in Virginia's communities and a better understanding of the magnitude of these health problems in Virginia will be gained.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

In light of the clear, specific and mandatory authority of the State Board of Health to promulgate the proposed amendments to the regulations, no alternatives are available that are advisable.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

The agency has found that there are no alternative regulatory methods that will accomplish the objectives of these amendments. The agency has put forth thoughtful consideration about the burdens of additional reporting and has limited these amendments to those necessary to protect the health and safety of Virginians.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

This Proposed Stage is not being used to announce a periodic review or a small business impact review.

The agency has assessed the need for the Disease Reporting and Control regulations and has found that they are critical to containing and mitigating communicable disease spread throughout the Commonwealth. VDH did not receive any comments following publication of the emergency amendments, which went into effect on January 20, 2021.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

Commenter	Comment	Agency response

No comments were received during the Emergency/NOIRA stage.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

The Virginia Department of Health is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Kristin Collins, 109 Governor St., Richmond, VA 23219, 804-864-7298, Kristin.collins@vdh.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
12VAC5-90-80		Reportable Disease List	Change: ● Add that COVID-19 (SARS-CoV-2) shall be reported as specified in subsection I of the section Intent:

			● to create regulatory requirements specific to COVID-19 Rationale: ● COVID-19 requires different reporting requirements than other reportable diseases Likely Impact: ● clarify responsibilities for persons reporting COVID-19 and ensure VDH gets necessary public health data
12VAC5-90-80		COVID-19 (SARS-CoV-2)	Change: ● Add subsection I: ● Require all suspect or confirmed COVID-19 case report forms be submitted electronically to VDH; ● Require all COVID-19 laboratory reports be submitted electronically to VDH; ● Clarify that the category "laboratory directors" includes all entities that hold CLIA Certificates of Waiver so that all entities testing for COVID-19 are required to report to VDH; ● Add the requirement that patient phone number, email address, and ethnicity be included in the list of fields that are reported by physicians, laboratory directors, and directors of medical care facilities. Intent: ● to clarify information required and methods of reporting for COVID-19 Rationale: ● COVID-19 requires different reporting requirements than other reportable diseases Likely Impact: ● clarify responsibilities for persons reporting COVID-19 and ensure VDH gets necessary public health data
12VAC5-90-90		Persons in charge of a medical care facility.	Change: ● Replace "hospital chart number" with "medical record number" Intent: ● to update a field to the current terminology Rationale:

			● clarify the term so that reporters know what information VDH is requiring Likely Impact: ● clarify responsibilities for persons reporting COVID-19 and ensure VDH gets necessary public health data
12VAC5-90-90		Persons in charge of hospitals, nursing facilities or nursing homes, assisted living facilities, and correctional facilities.	Change: ● Add "coronavirus, severe" to the list of infectious diseases that shall be reported to persons practicing funeral services Intent: ● to ensure persons practicing funeral services are informed about a potential exposure to COVID-19 Rationale: ● a dead body with COVID-19 could potentially expose a person performing funeral services and so additional precautions are necessary Likely Impact: ● Persons performing funeral services have necessary information to take necessary public health precautions to prevent the spread of an infectious disease

If a <u>new</u> VAC Chapter(s) is being promulgated and is <u>not</u> replacing an existing Chapter(s), use Table 2.

Table 2: Promulgating New VAC Chapter(s) without Repeal and Replace

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements

*If the regulatory change is replacing an **emergency regulation**, and the proposed regulation is <u>identical</u> to the emergency regulation, complete Table 1 and/or Table 2, as described above.*

*If the regulatory change is replacing an **emergency regulation**, but <u>changes have been made</u> since the emergency regulation became effective, <u>also</u> complete Table 3 to describe the changes made <u>since</u> the emergency regulation.*

Table 3: Changes to the Emergency Regulation

Emergency chapter-	New chapter-section	Current <u>emergency</u> requirement	Change, intent, rationale, and likely impact of new or changed requirements since emergency stage

section number	number, if applicable		
12VAC5-90-80		All SARS-CoV-2 tests, positive and negative, shall be reported by directors of laboratories, including pharmacies that hold CLIA Certificates of Waiver.	Change: ● Remove the requirement to report negative COVID-19 tests ● Remove the requirement to report hospitalizations and ICU admissions through the Emergency Department Care Coordination program. Intent: ● To ensure the requirement to get negative tests does not become permanent as the emergency has ended and this data will only be needed temporarily. ● To remove unnecessary language. Rationale: ● VDH will continue to collect this information for the CDC as it is still a requirement in the CARES Act and is used to report percent positivity. VDH does not require that negative tests are reported for any other communicable disease and believes that reporting percent positivity will be temporary. ● This has not been developed as a useful tool for this information and VDH has alternative means for collecting this data. Likely Impact: ● The workload for labs and VDH staff will decrease due to reporting of information that is no longer necessary. ● No other impact expected.