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Final Regulation
Agency Background Document

Agency name	State Board 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	August 3, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), 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 separates COVID-19 from the category “coronavirus, severe” on the reportable disease list; removes the requirement for COVID-19 to be rapidly reportable; 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 diseases 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.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

The Board of Health approved this Final Regulation for the Disease Reporting and Control Regulations at its quarterly meeting on September 22, 2022.

Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

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. The Governor's Office approved the use of emergency regulatory authority for these regulation changes.

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 is 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:
    - Separate "Coronavirus disease 2019 (SARS-CoV-2)" from "coronavirus infection, severe (e.g. SARS-CoV, MERS-CoV)" on the reportable disease list and conditions reportable by directors of laboratories list.
    - 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 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. By no longer receiving negative reports, the agency will not be able to report percent positivity. This could be a perceived disadvantage to the members of the public who were interested in that data element; however, the Centers for Disease Control and Prevention also no longer collect or report on that element.

The primary advantage to the agency is that the proposed amendments 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.

The proposed amendments will ultimately reduce the burden on physicians, laboratory directors, and directors of medical facilities as it removes the requirement to report negative COVID-19 test results,

which is the current regulatory requirement in the Emergency Regulation in effect until January 1, 2023 or until amended.

Requirements More Restrictive than Federal

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously reported information, 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.

Agencies, Localities, and Other Entities Particularly Affected

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously reported information, 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, physicians, medical facilities, and persons in charge of funeral homes are particularly affected by these amendments.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency's 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
Robert Wade DO	VDH has determined that it will no longer conduct contact tracing on COVID cases. While this was being done, the collection of demographics on positive cases from point of care testing was essential in this effort. However, since this tracing is no longer being	The Virginia Department of Health does continue to conduct contact tracing on COVID-19 cases, particularly as it relates to outbreak situations. This information is vital to our ability to continue that effort, as well as, allowing VDH to conduct disease investigations on person, place and time. The Federal CARES Act continues to require these demographic data elements (except for

	done, the demographics seem to no longer be useful. I understand reporting of positive cases and their demographics also stems from a requirement of the CARES Act. However, the supply of tests provided by the CARES Act are expiring or used up. Would this requirement also hold true for tests that are purchased with non CARES Act funds moving forward? In the matter of reporting influenza cases we are reporting aggregate positives to the district epidemiologist. I would like to propose that this be considered for reporting COVID case numbers.	email address) as it relates to COVID-19 reporting, regardless of how the tests are purchased.
Irene Kniss	Reporting all positive covid tests with demographics is an onerous task for health care providers. With the influx and wide use of at home testing, the reported positives by health care providers does not capture the full number of positive cases. Demographics are helpful for contact tracing but we know that contact tracing is not being done by the state department of health. If numbers are important than reporting aggregate negative and positive covid tests should be all that is necessary. Thanks for taking this under advisement.	The Virginia Department of Health does continue to conduct contact tracing on COVID-19 cases, particularly as it relates to outbreak situations. This information is vital to our ability to continue that effort, as well as, allowing VDH to conduct disease investigations on person, place and time. The Federal CARES Act continues to require these demographic data elements (except for email address) as it relates to COVID-19 reporting. These proposed amendments would no longer require disease reporters to report negative COVID-19 tests.
Andrew Guertler	It is clear that COVID-19 (SARS-CoV2) infection will be endemic. It has also become clear that contact tracing for this illness has been abandoned. There are highly effective vaccines and oral therapies have been and are being developed. The required reporting of all demographic information for people diagnosed with this disease is particularly onerous and time consuming with no obvious benefit. If contact tracing is not being performed in a very timely matter (within 24 hours) the utility vanishes. While large labs likely have this process automated, smaller labs in physician offices or small clinics do not. It does not make sense to require the	The Virginia Department of Health does continue to conduct contact tracing on COVID-19 cases, particularly as it relates to outbreak situations. This information is vital to our ability to continue that effort, as well as, allowing VDH to conduct disease investigations on person, place and time. The Federal CARES Act continues to require these demographic data elements (except for email address) as it relates to COVID-19 reporting. These proposed amendments would no longer require disease reporters to report negative COVID-19 tests. At this time, reporting individual level data (rather than aggregate as suggested) for COVID-19 is still warranted at this time and required by the federal government.

	reporting of information that is not being utilized. Furthermore, with the availability of OTC COVID-19 tests with no reporting mechanism, these cases are never tracked or acted upon. How does it make sense to track some while knowingly missing the OTC positive cases? As a better option, I propose the reporting of COVID-19 cases follow the same reporting as influenza did a few years ago. Labs report bulk positives and negatives. A modification would be that COVID-19 cases requiring hospitalization be reported with all demographics while all other cases are reported as bulk numbers. Medical offices do not need to be bogged down with administrative work that is not being used in a significantly worthwhile manner.	

Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. 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. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
12VAC5-90-80 A		• Add "(e.g., SARS-CoV, MERS-CoV)" after "coronavirus infection, severe" in section A *Add "Coronavirus Disease 2019 (SARS-CoV-2)" to the list in section A		Intent: • Clarify that COVID-19 is a separate reporting requirement from severe coronaviruses and that it is NOT rapidly reportable Rationale: • The volume of cases and severity of disease no longer require that VDH be notified within 24 hours; whereas, other

				coronaviruses that are more severe such as SARS-CoV and MERS-CoV still warrant that response Likely Impact: • Reduce the burden on disease reporters and add clarity between these disease types

Detail of All Changes Proposed in this Regulatory Action

*List all changes proposed in this action and the rationale for the changes. 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. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of updated requirements
12VAC5-80 A		Currently, the reportable disease list in section A only includes "*coronavirus infection, severe"	Change: • Add "(e.g., SARS-CoV, MERS-CoV)" after "coronavirus infection, severe" in section A; *Add "Coronavirus disease 2019 (SARS-CoV-2)" to the list in section A Intent: • Clarify that COVID-19 is a separate reporting requirement from severe coronaviruses and that it is NOT rapidly reportable Rationale: • The volume of cases and severity of disease no longer require that VDH be notified within 24 hours; whereas, other coronaviruses that are more severe such as SARS-CoV and MERS-CoV still warrant that response Likely Impact:

			• Reduce the burden on disease reporters and add clarity between these disease types
12VAC5-90-80 B		Currently, the conditions reportable by laboratories list in section B only includes "*coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)"	Change: • Add "Coronavirus disease 2019 (SARS-CoV-2)" to the list in section B Intent: • Clarify that COVID-19 is a separate reporting requirement from severe coronaviruses Rationale: • Clarify the two disease categories Likely Impact: • increase clarity for disease reporters
12VAC5-90-80 C		Currently, the rapidly reportable disease list in section C only includes "coronavirus infection, severe"	Change: • Add "(e.g., SARS-CoV, MERS-CoV)" to the list in section C Intent: • Increase consistency with other lists and clarify that COVID-19 is not included Rationale: • The volume of cases and severity of disease no longer require that VDH be notified within 24 hours; Likely Impact: • reduce the burden on disease reporters
12VAC5-90-80 I		Section does not currently exist in the VAC; however, was added in the Emergency Action still in effect.	Change: • Add subsection I: • Require all traditional data elements required for other reportable diseases plus ethnicity • Replace hospital chart number with medical record number • 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 all entities testing for COVID-19 are required to report to VDH; • Require all COVID-19 laboratory reports be submitted electronically to VDH;

			Intent: • to clarify information required and methods of reporting for COVID-19 Rationale: • COVID-19 requires different reporting elements and methods than other reportable diseases Likely Impact: • clarify responsibilities for persons reporting COVID-19 and ensure VDH gets necessary public health data
12VAC5-90-90 C			Change: • Replace hospital chart number with medical record number Intent: • Update outdated references Rationale: • The terminology has updated Likely Impact: • Provide clarity to disease reporters
12VAC5-90-90 F			Change: • Add “Coronavirus, severe (e.g., SARS-CoV, MERS-CoV) Intent: • Ensure necessary precautions are in place for persons handling potentially hazardous bodies Rationale: • Diseases like SARS-CoV and MERS-CoV are spread through respiratory droplets and can be extremely dangerous if the necessary precautions (PPE) are not in place Likely Impact: • Increase safety for persons practicing funeral services