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Emergency 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	June 25, 2020

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 the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an 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 amendment adds to the reporting requirements for physicians and directors of medical care facilities to require reports of hospitalizations, and ICU admissions, in addition to, reports of cases; requires case report forms be submitted electronically; clarifies that the category "laboratory directors" includes pharmacies that hold CLIA Certificates of Waiver; requires laboratory directors to report negative COVID-19 tests, in addition to positives; 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 (Necessity for Emergency)

Explain why this rulemaking is an emergency situation in accordance with § 2.2-4011 A and B of the Code of Virginia. In doing so, either:

- a) Indicate whether the Governor’s Office has already approved the use of emergency regulatory authority for this regulatory change.*
- b) Provide specific citations to Virginia statutory law, the appropriation act, federal law, or federal regulation that require that a regulation be effective in 280 days or less from its enactment.*

As required by § 2.2-4011, also describe the nature of the emergency and of the necessity for this regulatory change. In addition, delineate any potential issues that may need to be addressed as part of this regulatory change.

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 or 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, contains 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.

Further, § 32.1-42 of the Code of Virginia authorizes the Board of Health to promulgate regulations and orders to prevent a potential emergency caused by a disease dangerous to public health. The Board of Health is empowered to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the state health commissioner by § 32.1-12 of the Code of Virginia.

Also, § 32.1-13 empowers the Board to make separate orders and regulations to meet any emergency, not provided for by general regulations, for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious and infectious diseases and other dangers to the public life and health.

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

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:
 - In addition to reporting suspected or confirmed COVID-19 cases, require physicians and directors of medical care facilities to report COVID-19 hospitalizations and ICU admissions to the Virginia Department of Health through participation in the Emergency Department Care Coordination program;
 - Require all suspect or confirmed COVID-19 case report forms be submitted electronically to VDH;
 - Clarify that the category "laboratory directors" includes pharmacies that hold CLIA Certificates of Waiver so that pharmacies testing for COVID-19 are required to report to VDH;
 - Add the requirement that laboratory directors report both positive and negative COVID-19 test results;
 - 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, sever" 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.

Alternatives to Regulation

Describe all viable alternatives to the proposed regulatory action that have been considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

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.

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 emergency 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	<ul style="list-style-type: none"> • 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:

			<ul style="list-style-type: none"> • To require physicians and directors of medical care facilities to report suspected or confirmed COVID-19 cases, hospitalizations and ICU admissions to VDH; • Require all suspect or confirmed COVID-19 case report forms be submitted electronically to VDH; • Clarify that the category “laboratory directors” includes pharmacies that hold CLIA Certificates of Waiver so that pharmacies testing for COVID-19 are required to report to VDH; • Add the requirement that laboratory directors report both positive and negative COVID-19 test results; • 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.	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Change: Add “coronavirus, severe” to the list of infectious diseases that shall be reported to

		living facilities, and correctional facilities.	<p>persons practicing funeral services</p> <ul style="list-style-type: none"> • 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
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If a new VAC Chapter(s) is being promulgated and is not 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