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Fast-Track Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-90
Regulation title(s)	Disease Reporting and Control
Action title	Amendment to comply with changes in public health practice
Date this document prepared	8/21/2018

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 (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please 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 bring them into compliance with recent changes in the field of communicable disease detection and control and to allow greater flexibility with respect to reporting requirements in light of rapidly changing laboratory technologies and the emergence of new pathogens that are of public health concern.

This amendment removes, edits, and adds definitions as necessary to reflect current public health definitions and needs; removes the requirement to report weekly counts of influenza diagnoses; modifies the timelines for laboratories to submit isolates or specimens for further public health laboratory testing to improve the viability of material available for testing; replaces reporting by use of the Epi-1 form with reporting via an online web portal. The list of isolates or specimens that must be forwarded for further public health testing has been removed from 12VAC5-90-90 in this action because it is being added to

12VAC5-90-80 in a separate exempt regulatory action. The section on select agent reporting has been modified to clarify that VDH requires an annual report and an immediate report of a loss, theft, or release. Other, minor changes are listed below under Detail of Changes.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

No acronyms are used that are not defined in context.

Statement of Final Agency Action

Please 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.

Mandate and Impetus

Please 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, board decision, etc.). 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."

As required by Virginia Code § 2.2-4012.1, please also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

The impetus for this regulatory action is a board decision to bring the regulations into compliance with recent changes in the field of communicable disease detection and control, and to provide greater flexibility with respect to reporting requirements.

This regulatory action is being promulgated as a fast track because it is expected to be non-controversial. The proposed changes will assure timelier reporting of diseases while at the same time reducing the overall burden of disease reporting.

Legal Basis

Please identify (1) the agency or other promulgating entity, 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 entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity'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.

Purpose

Please 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 implement disease control for conditions of public health concern. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Substance

Please 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:

- Add, remove, and update definitions to enhance clarity;
- Specify new timelines for submission of isolates or specimens for state public health laboratory testing;
- Remove the list of isolates or specimens that must be forwarded for public health laboratory testing from 12VAC5-90-90 in this amendment because it is being added to 12VAC5-90-80 in another regulatory action;
- Remove the requirement that physicians and directors of medical care facilities submit weekly counts of cases of influenza;
- Replace reporting by way of the Epi-1 form with reporting through the VDH's online morbidity reporting portal;
- Add language that states that if a laboratory ascertains that the reference laboratory that tests a specimen reports to VDH electronically, then those reference laboratory findings do not need to be reported by the laboratory of origin;
- Add language that clarifies that if a facility director reports on behalf of the laboratory, the laboratory is still responsible for submitting isolates or specimens for public health testing "unless the laboratory has submitted an exemption request that has been approved by the department", thereby providing a process for opting out of the specimen forwarding requirement;
- Remove language referencing the commissioner's role in enforcement of isolation and quarantine because it has been removed from the Code of Virginia;
- Modify language to refer only to medications that are available in the United States for the treatment of ophthalmia neonatorum;
- Clarify that confirmatory testing is not required for blood lead levels that are below the CDC reference range on screening test;
- Limit the reporting of select agents to only an annual report and those scenarios in which such agents are released, lost, or stolen;
- Require that hospitals share with VDH any data they supply to CDC as a result of a requirement of the Centers for Medicare and Medicaid Services and not limited to the Hospital Inpatient Quality Reporting Program of that agency

Issues

Please 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 as well as removing the requirement to report weekly influenza counts or to report routine, non-emergency changes in select agent inventory. 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

Please 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.

None of these requirements is more restrictive than federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please 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

DCLS will receive isolates or specimens from other laboratories in a more timely fashion.

Localities Particularly Affected

The impact of these changes is anticipated to be the same for all localities.

Other Entities Particularly Affected

All healthcare providers and medical care facilities who are subject to these regulations would be equally impacted by these amendments.

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please 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. Please 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	Cost to the state will be related to communicating the changed requirements to the regulated community. Disease reporting requirements are usually summarized on posters and distributed to laboratories, infection preventionists, and others involved in disease reporting. The cost was $4,500 when the regulations were last amended: (1) $1800 to print 600 copies of the Regulations for Disease Reporting and Control, (2) $200 to print 600 posters of Conditions Reportable by Directors of Laboratories in Virginia, and (3) $2500 to print 20,000 posters of the Virginia Reportable Disease List. This cost will be paid by existing funds available at the time the regulations are finalized.
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 additional expenditures anticipated by any other state agency.
For all agencies: Benefits the regulatory change is designed to produce.	Benefits include more complete reporting of diseases of public health importance to VDH so that actions can be taken to minimize the spread of diseases in Virginia's communities and a better understanding of the magnitude of these health problems in Virginia will be gained.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	The proposed changes should not incur a cost to local governments. Local health department staff are already engaged in the duties relative to emerging infections and tracking reported cases of disease.
Benefits the regulatory change is designed to produce.	Benefits include more complete reporting of diseases of public health importance to VDH so that actions can be taken to minimize the spread of diseases in Virginia's communities and a better understanding of the magnitude of these health problems in Virginia will be gained.

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	The regulations pertain to physicians, laboratory directors, medical facility directors and directors of other settings where disease outbreaks may

affected, include a specific statement to that effect.	occur. The proposed amendments apply to each of those entities; however, the removal of the requirement that physicians and directors of medical care facilities submit weekly counts of cases of influenza, and limiting the reporting of select agents to only the Code-required annual report plus those scenarios in which such agents are released, lost, or stolen, and adding the requirement for morbidity reporting to be done through VDH's online morbidity reporting portal should reduce the burden of reporting among these entities.
Agency's best estimate of the number of such entities that will be affected. Please 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. Please 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 complete reporting of diseases of public health importance to VDH so that actions can be taken to minimize the spread of diseases in Virginia's communities and a better understanding of the magnitude of these health problems in Virginia will be gained.

Alternatives

Please 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, please 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.

VDH has assessed the requirements of the regulatory requirements and has not identified alternative methods of achieving the goals of this regulatory action. Reporting requirements have been removed when possible, such as for weekly counts of influenza diagnoses and routine reporting of select agent transfers, and the replacement of reporting by paper with reporting by way of an electronic portal should be less cumbersome for the regulated community. Complete and timely reporting is necessary to prevent and control the spread of communicable diseases, leaving few alternatives to exempt any healthcare providers from their responsibility to report disease to VDH.

Public Participation

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Detail of Changes

Please 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.

If the regulatory change will be a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory change. Delete inapplicable tables.

If the regulatory change is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below. Please include citations to the specific section(s) of the regulation that are changing.

For changes to existing regulation(s), please use the following chart:

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
12VAC5-90-10		Definitions	• Healthcare-associated infection (also known as nosocomial infection) –

			Replaced the term “hospital” with “medical care facility” to reflect infections that may occur in hospitals or nursing homes. • Hepatitis C, acute – Remove definition. This definition was needed when this infection was newly defined, but now the disease is better recognized and understood. • Hepatitis C, chronic – Remove definition. The infection is well understood in the regulated community so the definition is no longer needed. • Influenza A, novel virus – Modify definition to indicate that genetic reassortment of human and animal influenza viruses represent novel virus. Helps more clearly define what is meant by influenza A novel virus. • Lead, reportable levels – Remove definition. The proposed amendment requires all lead results to be reported, so the definition of a lead, reportable levels is no longer relevant. • Tubercle bacilli – Modify definition to include Mycobacterium bovis, Mycobacterium canetti, Mycobacterium microti, and Mycobacterium caprae as additional species included in the Mycobacterium tuberculosis complex. More clearly defines the tubercle bacilli of interest. • Tuberculin skin test (TST) – Remove definition. No longer needed because reporting is based on a positive result from any test. • Tuberculosis – Remove definition. This definition is not needed because more specific definitions for TB active disease and infection are already included in the regulations. • Tuberculosis, active disease – In the definition, change from “disease” to “communicable disease” to indicated that TB is spread from person to person. • Tuberculosis infection in children age <4 years – Modify definition name to Tuberculosis infection to account for the change being made in a separate regulatory action to require reporting of tuberculosis infection among all ages, not just persons <4 years of

			age. Also change "tuberculin skin testing" to "positive result from a test for tuberculosis infection" to reflect a broader range of acceptable diagnostic test types.
12VAC5-90-80		Directors of laboratories	• Change from submitting the isolate or clinical specimen within seven days to the Division of Consolidated Laboratory or other specified public health laboratory to submitting the isolate within five days and the clinical specimen within two days of a positive result.
12VAC5-90-90		Physicians	• Clarify that the list of elements to be reported on a case (e.g., name, address) represent the minimum reporting requirements. • Remove language stating that influenza should be reported by number of cases only. This is no longer required under this proposal. • Language added to reflect morbidity reporting through VDH's online morbidity reporting portal. • Add language referring to "disease-specific" surveillance form instead of surveillance form. • Modify language to reflect that reporting timeframes are as established in 12VAC5-90-80 rather than listing them again in this subsection.
12VAC5-90-90		Directors of laboratories	• Language added that if a laboratory ascertains that the reference laboratory that tests a specimen reports to VDH electronically, then those reference laboratory findings do not need to be reported by the laboratory of origin. • Language added to reflect morbidity reporting through VDh's online morbidity reporting portal. • Modify language to reflect that reporting timeframes are as established in 12VAC5-90-80 rather than listing them again in this subsection. • Language in subsection B pertaining to the submission of an initial isolate or other initial specimen to DCLS has been stricken because it has been updated and moved to 12VAC5-90-80 in a separate exempt regulatory action.

			• Add language that clarifies that if a facility director reports on behalf of the laboratory, the laboratory is still responsible for submitting isolates or specimens for public health testing "unless the laboratory has submitted an exemption request that has been approved by the department".
12VAC5-90-90		Persons in charge of a medical facility	• Remove language stating that influenza should be reported by number of cases only. This is no longer required under this proposed amendment. • Modify language to reflect that reporting timeframes are as established in 12VAC5-90-80 rather than listing them again in this subsection. • Add language to reflect morbidity reporting through VDH's online morbidity reporting portal. • Add language referring to "disease-specific" surveillance forms instead of surveillance forms.
12VAC5-90-90		Persons in charge of hospitals, nursing facilities or nursing homes, assisted living facilities, and correctional facilities	• List reportable organisms next to disease names so the reportable disease lists are equally meaningful to practicing clinicians and laboratorians.
12VAC5-90-103		Isolation for communicable disease of public health threat.	• Remove language referencing the commissioner's role in enforcement. This is no longer contained in the Code of Virginia.
12VAC5-90-107		Quarantine	• Remove language referencing the commissioner's role in enforcement. This is no longer contained in the Code of Virginia.
12VAC5-90-140		Procedure for preventing ophthalmia neonatorum	• Modify language to refer only to medications that are available in the United States.
12VAC5-90-215		Schedule and criteria for and confirmation of blood lead testing and information to be provided	• Change language "built before 1960" to "built before 1950". • Add language stating that confirmatory testing is not required if the result of the capillary test is below CDC's reference value. Reflects current national guidance on confirmatory testing. • Changed numbering under, "D. Confirmation of blood lead levels" to reflect the addition of language noted above.
12VAC5-90-225		Additional data to be reported related to persons with active tuberculosis	• Replace "tuberculin skin test (TST)" with ""tests for tuberculosis infection"

		disease (confirmed or suspected)	to reflect the availability of other tests for infection. • Remove the examples provided for Mycobacterium tuberculosis complex. Not needed because this is defined earlier in the regulations. • Replaced “tubercle bacilli” with “M. tuberculosis complex” • Add language that laboratories are required to submit results of tests for tuberculosis infection. • Changed numbering under, “B. Laboratories are required to submit the following” to reflect the addition of language noted above.
12VAC5-90-280		Reporting of dangerous microbes and pathogens	• Removed the definitions for “Biologic agent”, “CDC”, “Diagnosis”, “Proficiency testing”, “Responsible official”, “Toxin”, and “Verification” because they are no longer needed. • Clarified that “dangerous microbes and pathogens” are “select agents and toxins”. • Removed subsections on Administration, Reportable agents, Those required to report, and Exemption from reporting as they are no longer necessary. This section of the regulations is being streamlined to require annual reporting as specified in the Code of Virginia and reporting of instances in which agency response would be necessary. • Section D. Items to report. Renumbered to Section B. Removed the requirement that a report shall be made on a form determined by VDH, contain information on the objectives of the work with the agent, location (including building and room) where each select agent is stored or used, identification information of persons with access to each agent, identification information of the person in charge of the agents, or that the laboratory has to report that it is registered with the CDC Select Agent Program. These requirements are no longer needed. Added that the name and address of the laboratory must be reported. • Section E. Renumbered to Section C. Timing of reports. Language has been modified to define who at a laboratory submits the required reports annually

			and in instances involving a release, loss, or theft of a select agent of toxin, to whom at VDH and when. Language pertaining to reports that will no longer be required has been removed. • Section H. Release of reported information. Renumbered to Section D and the statement about exemptions from liability has been moved to this subsection.
12VAC5-90-370		Reporting of healthcare-associated infections	• The term "facilities" has been replaced with the term "acute care hospitals" to comply with the language in the Code of Virginia. The data that hospitals share with VDH will be any they supply to CDC as a result of a requirement of the Centers for Medicare and Medicaid Services and not limited to the Hospital Inpatient Quality Reporting Program of that agency.
12VAC5-90-370		FORMS	Removed reference to the following forms; Confidential Morbidity Report, Epi1 (rev. 10/2011), and the Virginia Cancer Registry Reporting Form (rev. 1/1998). These forms are no longer used by VDH.