Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) citation	12 VAC5-90
Regulation title	Regulations for Disease Reporting and Control
Action title	Amendment to comply with changes in public health practice
Date this document prepared	August 2, 2013

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The *Regulations for Disease Reporting and Control* provide information about the process and procedures for reporting diseases to the Virginia Department of Health, including what diseases must be reported, who must report them and other details related to public health reporting and disease control. The Virginia Department of Health is proposing an amendment to the regulations in order to bring them into compliance with recent changes in the field of communicable disease control and emergency preparedness that are needed to protect the health of the residents of Virginia.

The specific changes being proposed are necessary to ensure the regulations comply with recent changes in the practice of public health pertaining to the reporting of diseases in humans that are potentially transmitted from environmental sources (e.g., babesiosis and leptospirosis) as well as to update the list of laboratory tests that can be used to identify reportable disease findings and of specimens needing further testing to reflect advances in laboratory technology. Further amendments are necessary to clarify definitions and ensure consistency of the regulatory language, such as to standardize the reporting requirements for those who are required to report. Minor changes are also proposed to the section on the reporting of dangerous microbes to align the regulatory requirements with federal requirements. Renumbering is proposed for internal consistency and to ensure relevant sections are maintained as a whole.

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 without being defined in context.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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 new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The amendment is necessary in order to ensure that the regulations comply with changes in the *Code of Virginia* and recommendations of national public health organizations. The proposed changes improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for conditions of public health concern, including outbreaks and emergencies that could be caused by naturally occurring disease or acts of bioterrorism. 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 new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

- Update definitions to align them with current usage;
- Update the reportable disease list to reflect current national recommendations and language;

- Update the list of conditions reportable by laboratory directors to reflect current laboratory technology and public health standards;
- Increase the information reported by laboratory directors for hepatitis B and human immunodeficiency virus testing, especially for children, and the specimens to be submitted to the Division of Consolidated Laboratory Services for advanced laboratory testing;
- Update language to ensure consistency between sections;
- Clarify agency role in inter-state and national notifications;
- Clarify level of information that may be shared with the agency by schools and other facilities;
- Renumber sections to increase internal consistency within the regulations;
- Update reporting of dangerous microbes and pathogens sections to reflect federal code section numbering changes and other requirements.

Issues

Please identify the issues associated with the proposed regulatory action, 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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

The primary advantage to the agency is that the proposed amendments will improve the ability of the Virginia Department of Health to detect and control diseases of public health importance. Most of the changes being proposed are updates to terminology to reflect current usage or to clarify requirements. Some formatting changes have also been proposed.

The impact on businesses primarily affects laboratories conducting business in the Commonwealth. The addition of laboratory testing methods to the list of conditions that laboratory directors must report reflects advances in laboratory science, but would mean that laboratories conducting business in Virginia will have to report additional positive laboratory findings to the health department. To reflect current Centers for Disease Control and Prevention recommendations, the reportable blood lead level is changed from 10 to 5 µg/dL for children and from 25 to 10 µg/dL for adults. Many of the proposed changes are already being reported by laboratories who offer those testing options.

The proposed amendments would require laboratory directors to provide additional information on antimicrobial susceptibility for gonorrhea, details of hepatitis test results, and to submit remnant HIV diagnostic serum to DCLS for HIV recency testing and HIV genetic sequence data from HIV drug resistance tests. They would also report all hepatitis B test results for children under 2 years of age and HIV test results for children under 4 years of age.

The primary advantage to the public is that the Virginia Department of Health will be increasingly aware of conditions of public health concern so that staff can take action to reduce the risk of preventable acute diseases. No disadvantages to the public are known.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

None of these requirements is more restrictive than federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

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

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email or fax to Diane Woolard, Director, Division of Surveillance and Investigation, Virginia Department of Health, P.O. Box 2448, Room 516E, Richmond VA 23218; phone 804-864-8141; fax 804-864-8139; email diane.woolard@vdh.virginia.gov . Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board	The regulations pertain to physicians, laboratory directors, medical facility directors and directors of other settings where disease outbreaks may occur. The proposed amendments are anticipated to have minimal impact on these entities because the changes are minimal additions to existing disease reporting requirements. The two diseases being added to the reportable disease list, babesiosis and

	leptospirosis, occur at low frequencies and will not add appreciable volume to those required to submit disease reports to the health department. The largest impact is that laboratories will need to report additional positive laboratory findings and forward additional specimens to the Division of Consolidated Laboratory Services.
Agency's best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than $6 million.	Up to 100 laboratories may be affected by the changes proposed in laboratory reporting requirements; however, not all will offer the types of testing that must be reported. These laboratories are already reporting disease information to the health department, and the additions should have minimal impact. Some of the affected laboratories, including those in hospitals, would meet the definition of a small business.
Benefits expected as a result of this regulatory proposal.	Benefits include more complete reporting of diseases of public health importance to the health department 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.
Projected cost to the state to implement and enforce this regulatory proposal.	No costs are anticipated.
Projected cost to localities to implement and enforce this regulatory proposal.	No costs are anticipated.
All projected costs of this regulatory proposal for affected individuals, businesses, or other entities. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	The additional laboratory tests that must be reported will increase the volume of reports that must be submitted by laboratories to the health department, which will result in incremental increases in the cost of submitting reports. Laboratories would also be required to submit additional specimens to the Division of Consolidated Laboratory Services for additional testing, which means they would incur costs for shipping of such materials.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

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 have been considered, nor are there any 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

No lessening of reporting schedules is advisable given the health department's need to detect health problems in the community and respond quickly to the information reported under the requirements of these regulations in order to protect the health of the public. The schedules and requirements are as necessary and as simple as possible to achieve the goals of the regulations. The impact on small businesses is expected to be minimal.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
None	No comments were received following the publication of the NOIRA	

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed changes will indirectly protect and improve the health of the people of the Commonwealth. No adverse impacts on the institution of the family or on family stability are anticipated.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is 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 action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre**-emergency regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s) or regulations that are being repealed and replaced, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-90-10		Definitions	• Defines Centers for Disease Control and Prevention (CDC) and changes its usage upon later referral. • Corrects definition of 'central line device' to say 'great' vessels instead of 'greater'. • Changes capitalization on 'Ehrlichiosis/Anaplasmosis for consistency. • Updates definition of 'lead, elevated blood levels' to reflect current definition based on CDC reference value. • Updates definition of severe acute respiratory syndrome to include other novel coronavirus infections.
12VAC5-90-50	Repeal	Applicability Section	• This section stated that the regulations apply throughout the Commonwealth and are governed by the Administrative Process Act. Legislative Services advised that it is not necessary and is redundant with Code requirements.
12VAC5-90-80.A		Reportable disease list	• Additions to the reportable disease list will include babesiosis and leptospirosis. • Deletions will include monkeypox. The Department has other means of receiving data on the occurrence of this disease.
12VAC5-90-80.B		Conditions reportable by directors of laboratories	• Additions include babesiosis, hepatitis-other acute viral, and leptospirosis. • Deletions include monkeypox and methicillin-resistant *Staphylococcus aureus* infections. • Changes are proposed to the reportable results for botulism,

			Campylobacter infection, *E. coli* infection, giardiasis, gonorrhea, hepatitis B, hepatitis C, HIV, lead, salmonellosis, shigellosis, Staphylococcal infection, and Vibrio infection to incorporate current laboratory methods. • Laboratories would report all hepatitis B findings for children under 2 years of age and all HIV results for children under 4 years of age. • Laboratories would submit all remnant HIV sera to the Division of Consolidated Laboratory Services (DCLS) or other designated laboratory for HIV recency testing and would report all HIV genetic sequence data associated with HIV drug resistance testing.
12VAC5-90-80.C-F		Rapidly reportable conditions, toxic substances, outbreaks, and unusual diseases	• Deletes monkeypox. • Clarifies that rapid reporting means immediately by the most rapid means, using consistent language between sections.
12VAC5-90-90		Those required to report	• Changes are proposed in wording for consistency between all the subsections, including clarification of rapid reporting. • The term 'broth' is clarified and Vibrio is added to the list of isolates that must be submitted to the Division of Consolidated Laboratory Services (DCLS) for further testing. • Laboratories suspecting a diagnosis of a select agent would submit an isolate to DCLS for confirmation. • Clarifications are added that local health departments can report to the state using the electronic surveillance system and that the state is responsible for notifying other states and the Centers for Disease Control and Prevention. • Clarification of what information may be released to the health department by schools, camps, and facilities on individuals has also been added.
12VAC5-90-100		Methods of disease control	• Proposes to update language to refer to the 19th edition (2008) of the Control of Communicable Diseases Manual.

12VAC5-90-110		Immunization	• States that required immunizations may be obtained from physicians, registered nurses, or other licensed professionals authorized to administer immunizations.
12VAC5-90-280 through 12VAC5-90-360		Reporting of dangerous microbes and pathogens	• Strikes section numbers and changes them to letters for consistency within the regulations; • Proposes to update references to the Code of Federal Regulations to reflect changes in federal code section changes for select agent reporting; • Proposes to add language to clarify that select agent information is protected from release regardless of whether the information is submitted directly by laboratories or by federal agencies also holding the information. This is needed to ensure that terrorism-sensitive information is protected from access by potential terrorists seeking access to the materials.

If a new regulation is being promulgated, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
None added			