



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA) 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	Regulation amendment to comply with changes in public health practice
Date this document prepared	March 25, 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*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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 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 that will be 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 were potentially transmitted from animal vectors (e.g., babesiosis, leptospirosis, animal bites) as well as to update the list of laboratory tests that can be used to identify reportable disease findings 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. Changes will also be proposed to the regulatory requirements for the reporting of dangerous microbes to align them with federal requirements.

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*. The Office of the Attorney General has certified that the agency has statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

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 some that may indicate bioterrorism events. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Substance

Please detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

- 12VAC5-90-10: Minor changes in definitions
- 12VAC5-90-80: Repealed. Applicability Section – recommended by the State Registrar of Regulations. 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: Additions to the reportable disease list will include animal (mammal) bites, babesiosis, and leptospirosis. Deletions will include monkeypox and methicillin-resistant *Staphylococcus aureus* infections. The Department has other means of receiving data on the occurrence of the proposed deletions.
- 12VAC5-90-80.B: Changes to the list of conditions reportable by directors of laboratories will include the addition of babesiosis, hepatitis-other acute viral, and leptospirosis, deletion of

monkeypox, and changes to the reportable results for Campylobacter infection, *E. coli* infection, gonorrhea, hepatitis B, HIV, lead, Staphylococcal infection, and Vibrio infection.

- 12VAC5-90-80, Other Sections: – inserts the word ‘immediately’ to clarify the rapid reporting criteria
- 12VAC5-90-90: Changes are proposed in wording for consistency between all the subsections; 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 for further testing.
- 12VAC5-90-100: Proposes to update language to refer to the 19th edition (2008) of the Control of Communicable Diseases Manual.
- 12VAC5-90-310: Proposes to update references to the Code of Federal Regulations to reflect changes in federal code section changes for select agent reporting.
- 12VAC5-90-330: Proposes to delete the requirement for laboratories to report destruction of select agents or toxins to make Virginia regulations consistent with federal requirements.
- 12VAC5-90-360: 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.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please 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 have been considered, nor are there any that are advisable.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

Please also indicate, pursuant to your Public Participation Guidelines, whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel will be used in the development of the proposed regulation. Please state one of the following: 1) a panel will be appointed and the agency’s contact if you’re interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also 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) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation. A panel will not be used.

Anyone wishing to submit 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 day of the public comment period.

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

Family impact

Assess the potential 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.