



Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department 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 Virginia Code and public health practice
Date this document prepared	September 5, 2008

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) 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 how reporting is conducted. The Virginia Department of Health is proposing an amendment to the regulations in order to bring them into compliance with recent changes in the *Code of Virginia* and with recent changes in the field of communicable disease control and emergency preparedness that are needed to protect the health of the citizens of Virginia.

The specific changes that will be proposed are necessary to ensure the regulations comply with recent changes in the *Code of Virginia* pertaining to the reporting of outbreaks, isolation and quarantine provisions, prenatal testing for HIV infection, immunization requirements, and tuberculosis control. Further amendments are necessary to clarify definitions and edit reportable disease lists.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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*. 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. 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.

The amendments will:

- Update language to ensure that it reflects current public health, medical and scientific terminology;
- Update disease reporting requirements, including reportable diseases and those required to report;
- Update language regarding laboratory reporting requirements;
- Update tuberculosis reporting and control requirements and definitions;
- Update provisions regarding the reporting of toxic substance-related illness;
- Update requirements related to HIV prenatal testing; and
- Update other disease reporting and control provisions necessary to protect the health of the people of the Commonwealth.

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 advisable.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include 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.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a 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) 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 by mail, email or fax to Diane Woolard, PhD, MPH, Director, Division of Surveillance and Investigation, PO 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 the last day of the public comment period.

A public hearing will not be held.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

Most of the changes that will be proposed will ensure regulatory compliance with legislative mandates. Other changes seek to clarify requirements, such as by adding definitions. Input was received from other affected agencies and organizations during the legislative process. Input relative to laboratory requirements has been solicited from the Division of Consolidated Laboratory Services.

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.