



Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Department of Health (State Board of)
Virginia Administrative Code (VAC) citation	12 VAC 5-90
Regulation title	Disease Reporting and Control
Action title	Expanded Requirements for Reporting Healthcare-Associated Infections
Date this document prepared	August 10, 2009

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) 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 proposed regulatory action identifies additional measures related to healthcare-associated infections that acute care hospitals shall report to the Centers for Disease Control and Prevention (CDC) and the Virginia Department of Health (VDH). The amendment to the *Regulations for Disease Reporting and Control* is proposed in response to increased interest in measuring and improving patient safety in hospitals and reducing the occurrence of healthcare-associated infections.

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.

The *Code of Virginia*, § 32.1-35.1, requires acute care hospitals to report infection information to the CDC's National Healthcare Safety Network (NHSN) and for the State Board of Health to define infections to be reported and the patient populations to be included.

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 proposed regulations will allow the health department to view and analyze certain healthcare-associated infection data among hospitals. Hospital infection data will be available to the public upon request, providing greater transparency and accountability with respect to quality of care activities of hospitals and a means by which the public can monitor infection rates in a hospital. Potential issues that need to be addressed include: 1) educating the public on what the data can provide and the caveats that should be considered when attempting to compare hospital infection rates and control programs, and 2) ensuring adequate hospital staff availability to report additional measures through the NHSN system.

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 existing section of the regulations that addresses the reporting of healthcare-associated infections will be expanded to include additional measures of the occurrence of infections. The section will specify which units of which hospitals have to report what process and/or outcome measures, the mechanism that will be used to report the information, and a means of ensuring that VDH will have access to the data.

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.

The regulations are mandated per the *Code of Virginia*. The health department believes the regulations provide the best solution in response to the law. Regulated constituents were involved in the development of the proposed amendment.

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 meeting is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including costs and benefits and the potential impacts of this regulatory proposal. Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Diane Woolard, Ph.D., Director of the VDH Division of Surveillance and Investigation, PO Box 2448, Suite 516E, Richmond, VA 23218; diane.woolard@vdh.virginia.gov; fax (804) 864-8139. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by the last date of the public comment period. A public meeting will not be held to receive comments on this action.

Participatory approach

Please indicate the extent to which an ad hoc advisory group will be used 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.

The agency used a participatory approach in the development of the proposed amendment. The Executive Board of the Virginia Chapter of the Association for Practitioners in Infection Control and Epidemiology was consulted and an Advisory Committee jointly appointed by VDH and the Virginia Hospital and Healthcare Association discussed the alternatives and advised on the best solution. Recommendations from other states and national organizations were also considered.

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 regulations should have no impact on the family.