



Proposed Regulation 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	New Regulations for Reporting Healthcare-Associated Infections
Date this document prepared	June 4, 2007

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*.

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The proposed amendment to existing regulations identifies the process acute care hospitals shall use in reporting healthcare-associated infections to the Centers for Disease Control and Prevention (CDC) and the Virginia Department of Health (VDH). The type of infection and the methods and timing of reporting are defined.

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., the 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.

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 proposed regulatory action identifies the process acute care hospitals shall use in reporting healthcare-associated infections 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 a mandate of the Code. The goals are to provide a means for comparing specific healthcare-associated infection rates and possibly reduce the occurrence of these infections.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

A new section will be added to the regulations that addresses the reporting of healthcare-associated infections. The section will specify that all acute care hospitals with adult intensive care units will be required to join CDC's NHSN, report information about central-line associated bloodstream infections to the NHSN, and authorize VDH to have access to the data.

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 so indicate.

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) adequately training hospital staff to use the NHSN system.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no applicable federal requirements. The regulations are written in response to the *Code of Virginia*, 32.1-35.1 which requires hospitals to report infection rate information to CDC and the health department.

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.

Local health departments may be affected by the regulation if they are asked to assist in an investigation due a reported change in a hospital's infection rates.

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 regulation on farm or forest land preservation.

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, PhD, MPH, Director, 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.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	The costs to the state will be in developing and managing a database to store infection rate data and in analyzing and reporting the data. Additional costs may be incurred if an investigation is warranted.
Projected cost of the regulation on localities	There should be no economic impact on localities unless they assist in an investigation.
Description of the individuals, businesses or other entities likely to be affected by the regulation	All acute care hospitals with adult intensive care units will be affected by this regulation. Each facility will be required to join the NHSN network and follow the requirements of the system.

<p>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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Approximately 90 hospitals will be affected.</p>
<p>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</p>	<p>Hospitals may need to redirect their resources or hire additional staff to perform these activities. Computer equipment may need to be updated or purchased to meet the specifications of the NHSN system.</p>

The Agency accepts and has no comment to add relative to the Department of Planning and Budget’s Economic Impact Analysis.

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.

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.

Regulatory flexibility analysis

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.

The agency believes that the proposed regulation is the least burdensome option for acute care hospitals and the Virginia Department of Health to meet the requirements of the Code. The type of infection to be reported has been restricted to represent one that is of great importance in the provision of quality healthcare. The method that is to be followed to report involves an established infection reporting system such that no new standards or processes needed to be defined. Reporting frequency has been set to be the minimum acceptable for tracking data over time.

Public comment

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

Commenter	Comment	Agency response
	No comments received	

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.

These regulations should have no impact on the family.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

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

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
None	12 VAC 5-90-370	None	1) Acute care hospitals shall collect data on the following healthcare-associated infection in the specified patient population: central line-associated bloodstream infections in adult (age > 17 years) intensive care units, including the number of central-line days in each population at risk, expressed per 1,000. 2) All acute care hospitals with adult intensive care units shall a) participate in CDC's National Healthcare and Safety Network by July 1, 2008 and b) submit

			<p>data on the above named infection to the NHSN according to CDC protocols and c) ensure that all data for July-December 2008 are entered into the NHSN by January 31, 2009 and quarterly data entered thereafter according to a schedule developed by the department.</p> <p>3) All acute care hospitals reporting the information noted above shall authorize the department to have access to hospital-specific data contained in the NHSN database.</p>
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