



Final Regulation Agency Background Document

Agency name	Department of Health (State Board of)
Virginia Administrative Code (VAC) citation	12VAC5-90
Regulation title	Disease Reporting and Control
Action title	New Regulations for Reporting Healthcare-Associated Infections
Date this document prepared	October 25, 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 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

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 Board of Health. The type of infection and the methods and timing of reporting are defined.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

The State Board of Health reviewed and approved the final regulation at its October 19, 2007 meeting.

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 numbers, 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, the hospitals required to report, and the patient populations to be included.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal 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 Board of Health. 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 identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" 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 the Board of Health 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 there are no disadvantages to the public or the Commonwealth, please indicate.

The proposed regulations will allow the Board to view and analyze certain healthcare-associated infection data among hospitals. Hospital infection rate 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. Data will be aggregated to ensure that no individual patient may be identified. 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.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-90-370.B.2.	National Healthcare and Safety Network	National Healthcare Safety Network (deleted the word ‘and’)	Error in the name of the CDC system for reporting corrected
12VAC5-90-370.A.	Definition of central line-associated bloodstream infection refers to a ‘central line infusion device’	Changed to ‘central line device’, deleting the word ‘infusion’	To be consistent with the definition below it and with CDC terminology

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Director, Infection Control, Clinch Valley Medical Center	This may create an undue burden on facilities that do not have computer support; challenges of data verification and enforcement; potential for wasting time that could be invested in proven infection control practices.	Comment pertains to the legal mandate, not the method selected by the agency to implement the mandate. The implementation method should be the least burdensome and most accurate form of reporting possible to meet the mandate.
Valerie Spiegler, submitted on Town Hall	“The public must have easy access to infection rates.”	The regulation specifies that data will be available to the public upon request.
JoAnn Nadeau, submitted on Town Hall	Relates difficult experience with <i>Clostridium difficile</i> infection and suggests that this be made a reportable disease. States that Virginia must make hospitals and physicians report “statistics on their transmission and infection rates”.	Requiring the reporting of <i>C. difficile</i> infections is beyond the regulatory action that was proposed. This action is requiring hospitals to report certain healthcare-associated infections, consistent with the desires of this commenter.

All changes made in this regulatory action

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
None	12VAC5-90-370	None	<ol style="list-style-type: 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 Safety Network by July 1, 2008 and b) submit 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. 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.

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 Board 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.

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.