



Final Regulation Agency Background Document

Agency name	Department of Health (State Board of)
Virginia Administrative Code (VAC) citation	12VAC5-90
Regulation title	Regulations for Disease Reporting and Control
Action title	Expanded Requirements for Reporting Healthcare-Associated Infections
Date this document prepared	February 28, 2014

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*.

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 Agency is proposing that data reported into the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) for the Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Quality Reporting Program shall be shared, through the NHSN, with the department.

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 or board taking the action, and (3) the title of the regulation.

The State Board of Health approved the final amendment to the Regulations for Disease Reporting and Control on March 20, 2014.

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.

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. 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 regulatory action provides the Virginia Department of Health (VDH) with additional measures related to healthcare-associated infections (HAIs) from acute care hospitals without increasing the burden on the hospitals to provide the information. Data that hospitals entered into the Centers for Disease Control and Prevention's (CDC) HAI reporting system to meet hospital quality monitoring requirements of CMS would be made available to authorized staff members of VDH. Access to these data will allow VDH to have a means of measuring patient safety in hospitals, with the goal of helping to reduce the occurrence of healthcare-associated infections, without adding new reporting requirements for Virginia hospitals.

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.

The Agency is finalizing an amendment to 12 VAC 5-90-370, pertaining to the Reporting of Healthcare-Associated Infections. The amendment simply states that, "Data reported into the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) for the Centers for Medicare and Medicaid Services Hospital Inpatient Quality Reporting Program shall be shared, through the NHSN, with the department."

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 primary advantage to the public of implementing the amended provision is greater access to information about infections associated with hospitals in Virginia. No disadvantages to the public have been identified because the data will be confidential and will be presented in as clear and understandable a manner as possible. The primary advantages to the agency are greater access to information about infections occurring in Virginia hospitals and an increased ability to communicate with hospitals about potential means to improve surveillance for infections or prevent infections in their facilities. The primary disadvantage to the agency is increased workload in analyzing the additional data; however, gaining access to the data by way of the CDC system is the most efficient means identified for collecting the information. Another pertinent matter of interest to the regulated community is that, rather than adding more reporting requirements, potentially not aligned with those of the federal government, and increasing the reporting burden on hospitals in Virginia, VDH will receive data from Virginia hospitals by having them share the data they are already providing to CMS through the system they are using to report the data. This will provide VDH with additional data on the performance of Virginia hospitals through the system the hospitals already use, thus achieving the goal of measuring progress toward preventing infections without adding reporting burdens to an already stressed 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
12VAC5-90-999	Showed erroneous information about a Document Incorporated by Reference	Deleted this section	No documents are being incorporated by reference in this action

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
Halifax Regional Hospital	Support the amendment as written – it allows VDH to acquire the information needed without further burdening hospital staff	Accept comment; no changes necessary
Association for Professionals in Infection Control & Epidemiology, Virginia Chapter	Support the amendment as written – it provides VDH with additional measures related to healthcare-associated infections without increasing the reporting burden on hospitals	Accept comment; no changes necessary
Sentara-Rockingham Memorial Hospital	No issues granting rights to VDH to view hospital infection data mandated by CMS and reported to NHSN	Accept comment; no changes necessary
Augusta Health	Do not see the added value in allowing access to NHSN data – need clarity of how data would be utilized or how it would help the health department. Do not want to hinder/automate the relationship with the health department.	Considered the comment. Hospital-health department relationships would continue as they do now with respect to other disease reporting and investigations. VDH would use the data to track specific hospital infections in the state, guide prevention and educational efforts, and assist hospitals with reporting.
Virginia Department of Health, District Health Director	This requirement should be designed to ensure it does not interfere with hospital personnel calling the health department or limit the involvement of local public health officials.	Considered the comment. Hospital-health department relationships would continue as they do now with respect to other disease reporting and investigations. VDH would use the data to track specific hospital infections in the state, guide prevention and educational efforts, and assist hospitals with reporting.
Eastern State Hospital	Agree with the proposal – it should reduce or prevent duplicate reporting	Accept comment; no changes necessary
Danville Regional Medical Center	Support the proposed changes – they meet the charge for more data in a way that should not increase the burden on hospital staff	Accept comment; no changes necessary
John Randolph Medical Center	In favor of the amendment – it will be a good change	Accept comment; no changes necessary
LewisGale Medical Center	Responding with a personal opinion, not that of the health system – VDH intends to use the information responsibly in alignment with best practices. The data are very specific and could be misinterpreted – hope that VDH will present the SIR as a measure of infection as CMS does.	Accept comment; VDH plans to report the Standardized Infection Ratio (SIR), as CMS does.

All changes made in this regulatory action

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-90-370.B.	12VAC5-90-370.A.	Hospitals must report central line-associated bloodstream infections (CLABSI) in adult intensive care units	Data reported into the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) for the Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Quality Reporting Program shall be shared, through the NHSN, with the department,

Note: Definition deletions noted in the regulatory text designate changes made between an initial proposed amendment and a repropoed amendment. No changes were made after the reproposal, and no existing definitions included in the regulations are being amended in this action.