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## Proposed Regulation Agency Background Document

<b>Agency name</b>	Department of Health (State Board of)
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5 -90
<b>Regulation title</b>	Disease Reporting and Control
<b>Action title</b>	Expanded Requirements for Reporting Healthcare-Associated Infections
<b>Date this document prepared</b>	August 10, 2011

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

*In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.*

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 Hospital Inpatient Quality Reporting Program shall be shared, through the NHSN, with the department.

### Acronyms and Definitions

*Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.*

CDC – Centers for Disease Control and Prevention  
 CMS – Centers for Medicare and Medicaid Services  
 HAI – healthcare-associated infection  
 NHSN – National Healthcare Safety Network

**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.*

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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.*

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The proposed regulatory action provides the Virginia Department of Health (VDH) with additional measures related to healthcare-associated infections from acute care hospitals without increasing the burden on the hospitals to provide the information. Data entered into the Centers for Disease Control and Prevention’s (CDC) HAI reporting system for hospital quality monitoring by CMS would be made available to authorized staff members of VDH. This 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 briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the “Detail of changes” section.)*

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The Agency proposes to amend 12 VAC 5-90-370, pertaining to the Reporting of Healthcare-associated Infections. This is a re-proposal of an amendment based on comments received on a proposal that was published in the Virginia Register on January 31, 2011. That proposed amendment required additional reporting of HAIs to VDH by hospitals, and the comments received were not supportive of that action. The Agency has responded by submitting the current re-proposal, which 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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

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Hospitals are increasingly accountable to multiple organizations to demonstrate their performance relative to patient safety, including healthcare-associated infections. Hospital staff responsible for monitoring these infections are feeling the burden of increasing demands for data. In 2011, CMS began requiring hospitals to use the CDC's NHSN to report all central line-associated bloodstream infections in intensive care units in order to maximize their reimbursement for Medicare and Medicaid services. In 2012, CMS will expand those requirements to include the reporting of data on Catheter-Associated Urinary Tract Infections (CAUTI) and Surgical Site Infections (SSI) related to colon and abdominal hysterectomy procedures. CMS is also proposing additional reporting requirements for both acute care and long-term care facilities, to be rolled out over the next several years. Rather than add more requirements, potentially not aligned with the federal government, and increase the reporting burden on hospitals in Virginia, VDH proposes that Virginia hospitals will share these same CMS-required data with the Agency as well. This will provide VDH with additional data on the performance of Virginia hospitals by gaining access to the data hospitals enter into the CDC system for the CMS hospital quality program, thus achieving the goal of measuring progress toward preventing infections without adding reporting burdens to an already stressed 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.*

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This re-proposal clearly aligns state reporting with federal reporting requirements.

**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.*

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No locality would be particularly affected.

**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 regulated community.*

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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 via the Regulatory Townhall website, [www.townhall.virginia.gov](http://www.townhall.virginia.gov), or by mail, email or fax to Diane Woolard, PhD, MPH, Director, Division of Surveillance and Investigation, Virginia Department of Health, P.O. Box 2448, Suite 516E, Richmond, VA 23218; telephone (804) 864-8141; fax (804) 864-8139; email [diane.woolard@vdh.virginia.gov](mailto: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 date of the public comment period.

**Economic impact**

*Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</b></p>	<p>The Agency has federal funds to support this effort through July 2012. After that, the requirement could place a financial hardship on the Agency. Any available opportunities for funding to support the necessary staff resources will be pursued. If none are available, existing staff will be forced to absorb the responsibilities.</p>
<p><b>Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.</b></p>	<p>No cost to localities is anticipated.</p>
<p><b>Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.</b></p>	<p>Hospitals will be minimally impacted by the change to the existing regulation.</p>
<p><b>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.</b> 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 acute care hospitals will be impacted. Half of those have fewer than 200 beds.</p>
<p><b>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and do include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b></p>	<p>Hospital staff resources, particularly infection preventionists, will be needed to complete the required tasks.</p>

<p><b>Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</b></p>	
<p><b>Beneficial impact the regulation is designed to produce.</b></p>	<p>Increased information for healthcare consumers on hospital infections and quality performance.</p>

**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 Agency is not aware of any viable alternatives to the proposed amendment. 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.*

Multiple meetings and discussions have been held involving the Agency, hospitals of differing bedsizes, and other health-oriented organizations to develop the contents of this regulatory amendment. An existing reporting system that hospitals already use will provide the necessary information. Hospitals merely have to confer rights to the data to VDH, which is a function that can be performed through the CDC system. The amendment will allow the Agency to track the same performance measures that are being reported to the federal government.

**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
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	No comments were received.	
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**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.*

The amendment is not expected to have any impact on the family.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please detail the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations 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:

<b>Current section number</b>	<b>Proposed new section number, if applicable</b>	<b>Current requirement</b>	<b>Proposed change, rationale, and consequences</b>
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 Hospital Inpatient Quality Reporting Program shall be shared, through the NHSN, with the department.