Virginia Regulatory Town Hall

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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	Expanded Requirements for Reporting Healthcare-Associated Infections
Date this document prepared	April 26, 2010

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 State Board of Health is proposing to require hospitals to report three additional measures associated with healthcare-associated infections. The measures would include central line-associated bloodstream infections outside of intensive care units, *Clostridium difficile* infections that meet the CDC definition of a laboratory-identified event, and Surgical Care Improvement Process measures pertaining to hip arthroplasty, knee arthroplasty, and coronary artery bypass graft surgeries.

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
CLABSI – central line-associated bloodstream infection
HAI – healthcare-associated infection
NHSN – National Healthcare Safety Network

SCIP – Surgical Care Improvement Process

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. On April 23, 2010, the State Board of Health passed a motion to propose these regulations for public comment.

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 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.

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.)

The Agency proposes to amend 12 VAC 5-90-370, pertaining to the Reporting of Healthcare-associated Infections. The amendment would involve moving the definitions to 12 VAC 5-90-10 and adding reporting requirements for hospitals. The specific additional reporting requirements proposed are as follows:

- Central line-associated bloodstream infections in one adult inpatient medical ward and one adult inpatient surgical ward. Wards selected should be those with the longest length of stay during the previous calendar year, excluding cardiology, obstetrics, psychiatry, hospice, and step-down units. Data shall include the number of central-line days in each population at risk.
- *Clostridium difficile* infection, laboratory-identified events on inpatient units facility-wide, with the exceptions recommended by CDC protocol. Data shall include patient days.

- Acute care hospitals shall report to the department quarterly, within one month of the close of the calendar year quarter, aggregate counts of the Surgical Care Improvement Project (SCIP) Core Measures pertaining to the following surgical procedures: hip arthroplasty, knee arthroplasty, and coronary artery bypass graft. Data shall be collected in accordance with the Specification Manual for National Hospital Inpatient Quality Measures and shall include counts of the patient population and the applicable SCIP measures for each of the three surgical procedures. SCIP measures track compliance with procedures that have been shown to reduce the risk of infection following surgeries.

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.

As evidenced by a national movement, the public is very interested in increased reporting of HAIs and other measures of the quality of medical care. The advantage to the citizens is that more information would be available about hospital quality. The disadvantage to the regulated community (hospitals) is increased workload that would be created.

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.

No federal reporting requirement for HAI reporting currently exists.

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.

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, 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**. 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.

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.	The Agency has federal funds to support this effort through December 2011. 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.
Projected cost of the *new regulations or changes to existing regulations* on localities.	No cost to localities is anticipated.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	Hospitals will be impacted by the change to the existing regulation.
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.	Approximately 90 acute care hospitals will be impacted. Half of those have fewer than 200 beds.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and do include all costs. Be sure to include the projected reporting,	Hospital staff resources, particularly infection preventionists and performance improvement professionals, will be needed to complete the required tasks.

recordkeeping, and other administrative costs required for compliance by small businesses. 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.	
Beneficial impact the regulation is designed to produce.	Increased information for healthcare consumers on hospital infections and quality performance.

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 during the past year to develop the contents of this regulatory amendment. Quarterly reporting is being required when monthly reporting is recommended by CDC for some HAI measures. An existing reporting system that most hospitals already use will be used to report the additional infections. The measures being proposed have been discussed with the regulated community and have been determined to be important measures for the Agency to track.

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 were 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.

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:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
12VAC5-90-370.A.	12VAC5-90-10	Definitions pertaining to healthcare-associated infections are included in the HAI section of the Regulations	Definitions pertaining to healthcare-associated infections are being moved to the definitions section of the Regulations. New definitions have been added for C. difficile infections and SCIP measures.
12VAC5-90-370.B.	12VAC5-90-370.A.	Hospitals must report central line-associated bloodstream infections (CLABSI) in adult intensive care units	In addition, hospitals would be required to report CLABSI outside intensive care (in one adult medical ward and one adult surgical ward), *Clostridium difficile* infections identified by the laboratory, and Surgical Care Improvement Project measures pertaining to three surgeries: hip

			arthroplasty, knee arthroplasty, and coronary artery bypass graft.