Virginia Regulatory Town Hall

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# Proposed Regulation
# Agency Background Document

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| **Agency name** | Department of Health (State Board of) |
| **Virginia Administrative Code (VAC) citation** | 12 VAC 5 -90 |
| **Regulation title** | Regulations for Disease Reporting and Control |
| **Action title** | Regulation to Require the Reporting of Certain Methicillin-Resistant *Staphylococcus aureus* (MRSA) Infections |
| **Date this document prepared** | January 29, 2008 |

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 changes that are being proposed in this regulatory action.*

This proposed amendment will make permanent an emergency regulation that went into effect on October 24, 2007. It requires laboratory directors to report MRSA infections confirmed from specimens collected from normally sterile sites of the body, which indicate a serious, invasive form of the infection.

## 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 authorizes the Board of Health to promulgate a list of diseases that must be reported to the health department. The Department will use the data to compile statistics on the occurrences of these infections in different localities and populations across Virginia.

## 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.*

Methicillin-resistant *Staphylococcus aureus* (MRSA) has the potential to cause severe illness. The public has grown increasingly concerned about this threat to the health of their communities. The Virginia Department of Health is interested in promulgating regulations to require the reporting of the most severe MRSA infections confirmed by laboratories in order to better characterize and track the occurrence of these infections in Virginia communities.

## 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.)*

12VAC5-90-80.B. is being amended to add methicillin-resistant *Staphylococcus aureus* in normally sterile body sites to the requirement to report vancomycin-intermediate and –resistant *Staphylococcus aureus* infections. The reporting requirement applies only to laboratory directors.

## 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 primary advantage to the public is that there will now be an additional source of information about these infections, about which the public has concerns. The primary advantage to the agency is that this regulation will allow public health scientists to better characterize and track the occurrence of these infections in Virginia communities. The regulatory action poses no disadvantages to the public or the Commonwealth. This requirement will increase the workload for laboratory staff to report the infections.

## 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 requirements exist

## 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 has been identified as being 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 by mail, email or fax to Diane Woolard, PhD, Director, Division of Surveillance and Investigation, Virginia Department of Health, PO Box 2448, Suite 516E, Richmond, VA 23218, telephone (804) 864-8141, fax number (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 regulation.*

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| **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** | In-kind donation of staff time and resources, supported by general and federal funds, on an on-going basis. |
| **Projected cost of the regulation on localities** | In-kind donation of health department staff time and resources, supported by general and federal funds, on an on-going basis. |
| **Description of the individuals, businesses or other entities likely to be affected by the regulation** | Hospital and commercial laboratories, potentially physicians and other hospital employees. |
| **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. | 100 |
| **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.** | |

## 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.*

No other means is available to conduct consistent, continuous surveillance for these infections.

## 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.*

Periodic surveys and other voluntary reporting mechanisms were judged not sufficiently robust to accomplish the objective of tracking these infections.

## 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 |
|---|---|---|
| None | | |

## 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 regulation will not have an 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 |
|---|---|---|---|
| 12VAC5-90-80.B. | | Vancomycin-intermediate and -resistant *Staphylococcus aureus* (VISA and VRSA) infections are reportable | Methicillin-resistant *Staphylococcus aureus* in normally sterile body sites is added to the requirement to report VISA and VRSA |