



Final Regulation Agency Background Document

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 <i>Staphylococcus aureus</i> (MRSA) Infections
Date this document prepared	September 30, 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

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

This amendment makes 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.

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 final amendment was approved by the State Board of Health on October 17, 2008.

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 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. 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.

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 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.

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 there are no disadvantages to the public or the Commonwealth, please 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.

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
		No changes to note	

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.

Note: this table reflects comments received as of September 30, 2008. The comment period on the regulatory action ends October 3, 2008. Therefore, the table is subject to change.

Commenter	Comment	Agency response
Osteopathic physician	In favor of complete anonymous reporting of all illness, especially serious and moderately serious illness	Anonymous reporting does not meet the public health need for accurate information or for information that can lead to actions taken to prevent the spread of disease.
Public health laboratory manager	Agrees with the wording and the regulation	No agency action necessary.
Executive Medical Director and Medical Director of the Clinical Microbiology Laboratory of a specialty hospital	The reporting would provide a numerator without a denominator. Should also require reporting the total number of MRSA cases in aggregate monthly.	The agency hesitates to add any further reporting requirement for this condition. The suggested reporting of a monthly number would require different reporting procedures from other reportable conditions, and it would create an additional burden on laboratory and public health staff to ensure consistent compliance with the reporting requirement.
Private laboratory director	Rejects the proposed regulation. The reporting is not necessary.	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. See below (response to next commenter) for additional explanation regarding reporting requirement.
Health system	Very much against making the	Data disseminated by public health

laboratory director	reporting of MRSA, even from normally sterile sites, a permanent requirement. It is burdensome in time and costs and collects useless information. Public health efforts would be better served in citizen education on hand washing and personal hygiene.	surveillance systems are not always used for immediate public health action [CDC. Updated Guidelines for Evaluating Public Health Surveillance Systems: Recommendations from the Guidelines Working Group. MMWR Recommendations and Reports 2001;50(RR13);1-35]. In some situations these data are used to measure the burden of a disease, including changes in related factors, the identification of populations at high risk, or to monitor trends in the burden of a disease. Two examples in Virginia's current surveillance system include the requirements to report invasive Group A streptococcal disease, and invasive <i>Streptococcus pneumoniae</i> infection in children <5 years of age. Nevertheless, we do agree with the importance of educational efforts on handwashing and personal hygiene, and we have devoted resources to that priority from the outset.
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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
12VAC5-90-80.B.		Vancomycin-intermediate and -resistant <i>Staphylococcus aureus</i> (VISA and VRSA) infections are reportable	Methicillin-resistant <i>Staphylococcus aureus</i> in normally sterile body sites is added to the requirement to report VISA and VRSA

Enter any other statement here

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.

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.