Virginia Regulatory Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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	Emergency Regulation to Require the Reporting of Certain Methicillin-Resistant *Staphylococcus aureus* (MRSA) Infections
Date this document prepared	October 23, 2007

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

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.*

Preamble

The APA (Code of Virginia § 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.

1) Please explain why this is an "emergency situation" as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

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 have more data on the occurrence of these infections in Virginia communities.

Legal basis

Other than the emergency authority described above, 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., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The Code of Virginia section 32.1-35 authorizes the Board of Health to promulgate a list of diseases that shall be reported to the health department.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The emergency regulatory action requires laboratories to report MRSA infections confirmed from specimens collected from normally sterile sites of the body, such as blood or joint fluid. The Department will use the data to compile statistics on the occurrences of these infections in different localities and populations across Virginia.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The action is being taken as a result of concern following the recent death of a Virginia teenager due to invasive MRSA and a peer-reviewed medical publication finding that invasive MRSA is a major public health problem in the United States. MRSA infections are occurring across the state and a more systematic means of capturing and compiling reports is needed. The reporting of confirmed invasive infections will allow the Department to respond to requests and expectations for data from the concerned public, health care professionals, and policymakers. Potential issues include the burden on laboratories to report results, and the identification of sufficient resources within the health department to compile and track data on these conditions.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

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.	Same	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

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider, other alternatives for achieving the need in the most cost-effective manner.

Alternatives may include periodic surveys of clinical laboratories, but that would not result in as timely data. Citizens could report cases of concern, but those would not be verified by clinical testing. When the health department needs to conduct surveillance for a communicable disease, the mechanism used is the reportable disease list in the Regulations for Disease Reporting and Control.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

The agency/board will seek comments at a later time, i.e., public comment on the emergency regulation before it is made permanent, but is always willing to hear suggestions (best directed to the VDH staffer identified in this Town Hall action, via email). At that time, data regarding issues including but not limited to 1) ideas to assist in the development of a proposed regulation, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency/board is also 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 for the public comment file may do so by mail, email or fax to Diane Woolard, PhD., 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; **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 day of the public comment period.

A public meeting will not be held pursuant to an authorization to proceed without holding a public meeting.

Participatory approach

Please indicate the extent to which an ad hoc advisory group will be used in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The agency/board is not using the participatory approach in the development of the proposal pursuant to an authorization to proceed without the participatory approach;

Family impact

Assess the potential 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.

This regulatory action has no impact on the family.