Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-90
Regulation title	Disease Reporting and Control
Action title	Regulation amendment to comply with changes in Virginia Code and public health practice
Date this document prepared	March 12, 2009

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.

The *Regulations for Disease Reporting and Control* provide information about the process and procedures for reporting diseases to the Virginia Department of Health, including what diseases must be reported, who must report them and how reporting is conducted. The Virginia Department of Health is proposing an amendment to the regulations in order to bring them into compliance with recent changes in the *Code of Virginia* and with recent changes in the field of communicable disease control and emergency preparedness that are needed to protect the health of the citizens of Virginia.

The specific proposed changes are necessary to ensure the regulations comply with recent changes in the *Code of Virginia* pertaining to the reporting of outbreaks, isolation and quarantine provisions, prenatal testing for HIV infection, immunization requirements, and tuberculosis control. Further amendments are necessary to clarify definitions and edit reportable disease lists.

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.

Chapter 2 of Title 32.1 of the *Code of Virginia*, §§ 32.1-12 and 32.1-35 through 32.1-73, contains mandatory language authorizing the State Board of Health to promulgate the proposed regulations. Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth are to be reportable and the method by which they are to be reported. Further, § 32.1-42 of the *Code of Virginia* authorizes the Board of Health to promulgate regulations and orders to prevent a potential emergency caused by a disease dangerous to public health. The Board of Health is empowered to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the state health commissioner by § 32.1-12 of the *Code of Virginia*. The Office of the Attorney General has certified that the agency has statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

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 amendment is necessary in order to ensure that the regulations comply with changes in the *Code of Virginia*. The proposed changes improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for conditions of public health concern, including some that may indicate bioterrorism events. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

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.)

Amendments to current regulations will:

- Update language to ensure that it complies with Code and reflects current public health, medical and scientific terminology;
- Update disease reporting requirements, including reportable diseases and those required to report;
- Update language regarding laboratory reporting requirements;
- Update tuberculosis reporting and control requirements and definitions;
- Update provisions regarding the reporting of toxic substance-related illness;
- Update requirements related to HIV prenatal testing and gamete donation; and

- Update other disease reporting and control provisions necessary to protect the health of the people of the Commonwealth.

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 proposed changes improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for conditions of public health concern, including some that may indicate bioterrorism events. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Except as noted in the paragraphs below, changes are alterations in language and terminology to reflect current scientific use and to provide clarification. For example, the phrase “interrupt the transmission of disease” is replaced by “reduce the occurrence of disease”, names of conditions on the Reportable Disease List are modified to comply with scientific usage, and definitions that were in a subsection are moved to the Definitions section. These changes improve the clarity of the regulations but are not substantive.

Updates to disease reporting requirements:

- Conditions requiring rapid communication will be reported “by the most rapid means available”, rather than “within 24 hours” to clarify that immediate action is expected for these high priority conditions.
- The change in terminology from “poliomyelitis” to “poliovirus infection” clarifies that all poliovirus infections are reportable, not only those resulting in paralysis.
- Toxic Shock Syndrome is removed from the list of reportable conditions, but is added as a reportable Group A Streptococcal infection. Toxic shock may result from streptococcal or staphylococcal organisms. The number of staphylococcal toxic shock syndrome cases has been minimal over the past 10 years (averaging 1.2 cases per year) and clinical management is effective to limit spread. Streptococcal infections are still of public health concern and will remain reportable.
- Kawasaki syndrome is removed from the list of reportable conditions. The conditional was initially added as a reportable condition due to a national research effort to identify the causal agents. However, no cause has been identified and there is no public health intervention to reduce the occurrence of disease. Over the past 5 years, an average of 17 Kawasaki cases was reported each year in Virginia.
- Changes in reporting requirements for laboratory directors pertain to Lyme disease and heavy metals. Lyme disease is added to the list of conditions reportable by laboratories because laboratory findings are essential for identification and confirmation of cases. Because the major reference laboratories currently submit Lyme disease findings, the impact is expected to be minimal. When reporting elevated levels of heavy metal exposure, the amendment proposes requiring laboratories to provide speciation, indicating whether the metal is organic or inorganic, when this information is available. This assists in determining whether public health action is needed to follow up on reports, which applies only to inorganic metals.
- To comply with changes in Virginia Code § 32.1-37, new wording is added to specify that persons in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth must report outbreaks. The change in Virginia Code, which was made during

the 2008 legislative session, addressed a gap in the requirement for persons in charge of schools, child care centers, and summer camps to reports outbreaks. Earlier involvement by public health minimizes the number of individuals who become ill and assists the facility in implementing changes to reduce future outbreaks.

Submission of tuberculosis specimens: To comply with changes in Virginia Code § 32.1-50, the updated regulations remove the exception that previously allowed a laboratory to submit drug susceptibility findings for tuberculosis specimens in place of a viable sample. Submission of positive cultures for a member of the *M. tuberculosis* complex to the Division of Consolidated Laboratory Services (DCLS) or other approved laboratory guarantees the availability of drug susceptibility results for public health and treating clinicians. These results are important to ensure the appropriate treatment of individuals impacted by tuberculosis disease. In addition, genetic fingerprinting of the organism by public health laboratories provides insights into disease transmission patterns and identifies points where public health intervention can prevent further transmission.

Submission of specimens for additional confirmation: Laboratories identifying evidence of 14 conditions in addition to tuberculosis have been required to submit specimens to DCLS. In this action the requirement is expanded to include four additional conditions. Two are potential bioterrorism conditions not currently included on the list (brucellosis and Q fever). The third is novel influenza A viruses, which could herald the arrival of a new strain of influenza that could potentially lead to a large-scale epidemic or pandemic. The fourth is vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus*. VDH receives less than 24 reports per year of these four conditions combined. Resistance to vancomycin in *Staphylococcus aureus* is an emerging health concern; however, most preliminary findings of resistance are ruled out with confirmatory testing. The other changes in this section offer clarifications. Typhoid fever is caused by *Salmonella typhi*, and was intended to be covered in the requirement for evidence identifying salmonellosis, but specific mention of the organism will ensure specimen submission. For *E. coli* O157, the new requirement specifies that when EIA testing is done without culture, the positive broth may be submitted; previously the regulations referred only to the submission of specimens for further testing. Additional testing performed at the state laboratory for these 17 conditions is essential for identifying and delineating outbreaks. On a national level, the ability to obtain and act on this type of analysis is expected of state health departments.

Isolation and quarantine: Changes to the regulations specify that if the risk of infection or transmission continues at the end of the confinement, new orders may be issued to extend the confinement. The procedures for extending orders protect the individual while minimizing health risks to the public. These changes make isolation and quarantine orders more practical to implement and enforce.

Immunization requirements: The regulations are updated to be in conformance with changes in Virginia Code § 32.1-46, which updated the immunization requirements for children. Additionally, the immunization requirements for school entry in 12 VAC5-110-70 are referenced, rather than repeated... This section makes reference to the changes in immunization requirements in § 32.1-46 and those in 12VAC5-110-70, which is under separate review, but does not modify the requirements themselves nor incur any additional costs. The changes reduce duplication in regulations and eliminate the need to modify both sets of regulations when immunization requirements are updated.

Prenatal testing for HIV infection: The regulations are updated to be in conformance with changes in Virginia Code § 54.1-2403.01, which was amended in the 2008 Session of the General Assembly, and with current guidelines of the Centers for Disease Control and Prevention (CDC). HIV testing during pregnancy is a standard of medical care, and universal screening with an opt-out provision is supported by the American College of Obstetricians and Gynecologists. The change in regulation language would change HIV testing during pregnancy from opt-in to opt-out, and increase from one to two the number of HIV tests to be performed on pregnant women. This change would potentially benefit women by identifying HIV infection, and benefit their newborns through identifying those who would require HIV preventive treatment. The change would ultimately benefit society by decreasing the number of children with HIV infection. This regulation would bring Virginia in line with CDC guidance as well as Virginia Code, which makes prenatal HIV testing a routine opt-out procedure. In guidance released in 2006, the

CDC identified states where two HIV tests should be performed during pregnancy, because those states have an elevated incidence of HIV or AIDS among women 15 – 45 years of age. Virginia was one of the identified states, and the Association of Maternal and Child Health Programs, to which the Title V Maternal and Child Health Block Grant recipients belong, recommends that state and national policymakers take steps to implement universal opt-out screening which includes the second HIV test during the third trimester in the jurisdictions identified by CDC. The only disadvantage to the public or the Commonwealth is the cost of the HIV testing.

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.

None of these requirements is more restrictive than federal 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.

The impact of these changes is anticipated to be similar for all localities.

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, MPH, Director, Division of Surveillance and Investigation, PO Box 2448, Room 516E, Richmond VA 23218; phone (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.

A public hearing will not be held.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

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	An additional FTE was provided to DCLS to conduct the additional testing of tuberculosis specimens when the tuberculosis statute was changed. No additional state costs are projected with the corresponding update to the regulation. Testing of the other additional specimens required to be submitted to DCLS will be supported with grant funds. Virginia Department of Health has been offering HIV screening to pregnant women already, with a good acceptance rate, so there could be a small cost increase if an increased number of women accepted the initial screening. While some health districts provide maternity care, most will refer to another provider at some point in the pregnancy, so the majority of pregnant women would likely be receiving care from another provider at the time they would be offered the second HIV test. The Department of Medical Assistance Services (DMAS) could expect to have increased costs for HIV testing in pregnant women if the second HIV test became routine practice.
Projected cost of the regulation on localities	As stated above, most health districts do not manage care for the entire pregnancy, so there would not be a substantial anticipated cost for implementation of the modified HIV testing requirement.
Description of the individuals, businesses or other entities likely to be affected by the regulation	Laboratories doing business in Virginia will be affected by the requirement to submit additional specimens for supplemental testing. Insurance companies and health care providers would be expected to be affected by the regulation requiring increased HIV testing.
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.	The major reference laboratories are already submitting reports on Lyme disease and they account for the majority of testing for this condition, so few small businesses will be affected. Up to 50 laboratories may be affected by the requirement to submit tuberculosis specimens to DCLS or other approved laboratories. Most tuberculosis testing is done by large national reference laboratories and by hospital laboratories. Therefore, it is unlikely that many, if any, small businesses will be affected by this requirement. Similarly, organism identification is generally performed by large national reference laboratories

	and by hospital laboratories so it is unlikely that many, if any, small laboratories will be affected by the requirement to submit specimens for the three additional conditions. All providers of pregnancy care would be affected through offering the HIV tests to their patients.
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.	The major reference labs are already submitting reports on Lyme disease. The burden of reporting will be reduced with electronic transmission of findings. Submission of laboratory specimens to DCLS or other approved laboratories will require personnel time and materials for packaging the specimens and shipping fees. There were 140,416 pregnancies in Virginia in 2006, with the cost per HIV test varying greatly according to payer source.

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.

In light of the clear, specific and mandatory authority of the State Board of Health to promulgate the proposed amendments to the regulations, no alternatives have been considered, nor are any advisable.

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.

These changes in regulation are expected to have little impact on small businesses. The regulations have been designed to minimize costs to all businesses. Most of the changes that would have an impact are already required by the *Code of Virginia*. No additional mechanisms to reduce the burden to small businesses are available.

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 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 proposed changes will indirectly protect and improve the health of the people of the Commonwealth. No adverse impacts on the institution of the family or on family stability are anticipated.

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
12VAC5-90-10		Definitions	• Move definitions related to reporting of healthcare-associated infections to this section from 12VAC5-90-370. • "Affected area" – Modify definition to indicate what may constitute an "area". • "Arboviral infection" – Add definition to clarify disease reporting requirements. • Ehrlichiosis/anaplasmosis – Add definition to clarify disease reporting requirements.

			• "Influenza A, novel virus" – Add definition. • "Midwife" – Amend definition to reflect current licensing requirements. • Nosocomial outbreak – Remove definition. Term is outdated. • Isolation and Quarantine – Modify both to change "communicable disease of public heath threat" to "communicable disease".
12VAC5-90-30		Purpose	Replace "interrupt the transmission of disease" with "reduce the occurrence of disease" to more accurately portray the objective of these regulations
12VAC5-90-80 (A)		Reportable disease list	• Change disease names to comply with scientific usage and ensure internal consistency. • Change reporting requirement for conditions requiring rapid communication. They must be submitted "by the most rapid means available", rather than "within 24 hours", to allow rapid mobilization of the public health response. • Remove Kawasaki syndrome from the list of reportable conditions. There is no public health action for this condition. • Change "Poliomyelitis" to "Poliovirus infection, including poliomyelitis" to clarify that non-paralytic poliovirus infections are to be reported. • Remove Toxic shock syndrome from the list of reportable conditions. Reporting of streptococcal toxic shock continues with the reporting of Group A streptococcal infections. Staphylococcal toxic shock will no longer be reported.
12VAC5-90-80 (B)		Conditions reportable by directors of laboratories	• Change disease names and reporting specifications to comply with scientific usage and ensure internal consistency. • Change reporting requirement for conditions requiring rapid communication. They must be submitted "by the most rapid means available", rather than "within 24 hours", to allow rapid mobilization of the public health response • Add Lyme disease to facilitate case identification and confirmation. • Change "Poliomyelitis" to "Poliovirus infection" to clarify that non-paralytic poliovirus infections are to be reported. • Require results of speciation for heavy metals, when performed, to improve classification
12VAC5-90-80 (C)		Reportable diseases requiring rapid communication	• Change disease names and reporting specifications to comply with scientific usage and ensure internal consistency. • Change reporting requirement for

			conditions requiring rapid communication. They must be submitted "by the most rapid means available", rather than "within 24 hours", to allow rapid mobilization of the public health response • Add "Influenza A, novel virus" to assist in detection and identification of potential pandemic influenza strains. • Add congenital rubella syndrome by including it with the listing for rubella, as it is presented on the reportable disease list in 12VAC5-90-80(A), to allow rapid response
12VAC5-90-90 (B)		Those required to report – directors of laboratories	• Re-format for clarity • Expand requirement for submission of specimens for confirmation and further characterization by laboratories to include evidence of brucellosis and Q fever, two bioterrorism conditions, novel influenza A viruses, an indicator of a possible pandemic situation, and vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus,* an emerging condition. • Clarify that specimens are to be submitted for typhoid fever, a condition caused by a *Salmonella* organism, to allow confirmation and further characterization. • For shiga toxin producing *E. coli*, allow laboratories using EIA methodologies without performing culture to submit positive broths or stool specimens (the current regulation states only stool) to DCLS for confirmation and further characterization. Additional characterization performed by DCLS is important for the identification and delineation of potential outbreaks. • To improve compliance, reflect the requirements for tuberculosis specimen submission from 12VAC5-90-225 in this section.
12VAC5-90-90 (D)		Those required to report – persons in charge of a facility	• Make explicit the expectation that persons required to report outbreaks include those managing state operated or state licensed facilities or services. Addresses a gap in the identification and response to disease outbreaks. • Add citation for the Section of Virginia Code defining camps. • Clarify that information on the affected individuals may be provided. This is needed for investigation of outbreaks.
12VAC5-90-90 (E)		Those required to report – local health directors	• Change reporting requirement for conditions requiring rapid communication.

			Specify that they must be submitted "by the most rapid means available" to be consistent with 12VAC5-90-80(C)
12VAC5-90-103		Isolation for communicable disease of public health threat	• Modify wording for clarity and compliance with Code. • Provide clarification regarding appropriate parties for delivery of isolation orders • Specify that new orders may be issued to extend the confinement if risk persists
12VAC5-90-107		Quarantine	• Modify wording for clarity • Provide clarification regarding appropriate parties for delivery of quarantine orders • Specify that new orders may be issued to extend the confinement if risk persists
12VAC5-90-110		Dosage and age requirements for immunizations; obtaining immunizations	• Change "child" to "person…less than 18 years of age" to be consistent with the Advisory Committee on Immunization Practices nomenclature. • Change immunization requirements to be consistent with *Code of Virginia* § 32.1-46. • Remove listing of immunization requirements for school entry, and reference section 12 VAC 5-110-70, where these requirements are specified. This eliminates duplication and reduces the need to update both sets of regulations with changes to the immunization requirements for school entry.
12VAC5-90-130		Prenatal testing	• Modify wording for clarity • Expand explanation of persons at high risk for syphilis to include persons in high prevalence communities and populations. • Make HIV testing an "opt-out" component of the prenatal panel rather than an "opt-in" component. This will encourage testing and is consistent with national guidelines and medical standards of care and with the *Code of Virginia*. • Recommend a second HIV test in the third trimester to be consistent with CDC recommendations for areas with elevated incidence of infection.
12VAC5-90-140		Procedure for preventing ophthalmia neonatorum	• To ensure consistency with language used in other Virginia Department of Health regulations (12VAC5-71-50) regarding procedures for newborns and with the recommendations of the American Academy of Pediatricians.
12VAC5-90-225		Additional data to be reported related to persons with active tuberculosis disease (confirmed or	• To be consistent with Code of Virginia §32.1-50, require laboratories to submit a viable sample of a positive culture for a member of the *M. tuberculosis* complex.

		suspected)	
12VAC5-90-370		Reporting of healthcare-associated infections	• Move definitions to 12VAC5-90-10 to be consistent with other parts of these regulations. • Clarify that data are not necessarily entered quarterly, but that data must be available quarterly. It is preferred that data are entered monthly, in accordance with the protocols of the National Healthcare Safety Network.

Enter any other statement here