Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	12 VAC 5-90
VAC Chapter Number:	Chapter 12
Regulation Title:	Disease Reporting and Control
Action Title:	Amending Regulations for Disease Reporting and Control
Date:	March 19, 2003

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form,Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

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 to the Code of Virginia and with recent changes in the field of communicable disease control and emergency preparedness that need to be implemented to protect the health of the citizens of Virginia.

The proposed amendment includes the addition and clarification of several definitions, updates to the reportable disease list and the list of diseases requiring rapid reporting, the addition of a requirement to report diseases that may be due to a biologic agent used as a weapon, the addition of information about how laboratories shall report their inventories of dangerous microbes and pathogens, the addition of a section about the reporting and control of tuberculosis, an update to the list of conditions reportable by laboratories and the tests used to confirm those conditions, and the addition of a requirement for private laboratories to submit designated specimens to the state laboratory for confirmation and further testing. Due to the need for information in order to act to protect the public, an amendment is proposed to require the reporting of diseases within three days instead of seven days.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Chapter 2 of Title 32.1 of the Code of Virginia, Sections 32.1-35 through 32.1-73, contains mandatory language authorizing the State Board of Health to promulgate the proposed regulations. Specifically, Section 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occuring in the Commonwealth are to be reportable and the method by which they are to be reported. Further, Section 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. Section 32.1-12 of the Code of Virginia empowers the Board of Health to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the commissioner of the Department of Health. The Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

In response to the 2002 General Assembly amending §32.1-35 and 32.1-36 of the Code of Virginia, amendments to the Regulations for Disease Reporting and Control are being proposed, requiring laboratories to report their inventories and changes in inventories of dangerous microbes and pathogens to the Department of Health. Additionally, changes are proposed to the existing disease reporting and control regulations so that they comply with current public health practices, facilitating efforts to capture, measure and contain emerging diseases and protecting the health of the citizens of the Commonwealth.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

Proposed amendments to the Regulations for Disease Reporting and Control include: adding and changing definitions to clarify the disease reporting process; amending the list of diseases which are reportable by laboratories, including adding new diseases and updating confirmatory tests; requiring private laboratories to submit designated specimens to the state laboratory for confirmation and further testing, which is currently required only for hospital laboratories; updating requirements of physicians and medical care facilities for the reporting and management of tuberculosis; updating requirements for reporting of cancer; and adding a section defining the procedures for laboratories to report inventories of dangerous microbes and pathogens. Amendments are necessary in order to bring the Regulations for Disease Reporting and Control into compliance with current public health practices and emergency preparedness expectations.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

Advantages to citizens is that the public health system will be conducting surveillance on additional conditions of public health concern, some of which may indicate bioterrorist events, and thus will be in a better position to detect and then respond to reports of these illnesses in a way to protect the health of the public. Disadvantages to businesses is that physicians' offices, laboratories, and hospitals will have additional information to report to the health department and will have to do so in a more timely manner. The overall advantage to the Commonwealth is increased disease detection, which will trigger response by public health officials.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

The Virginia Department of Health plans to absorb the additional responsibilities that result from the amendment. The additional costs to businesses should be minimal in that reporting is already required and procedures are in place to report. The amendment requires additional diseases, most of which occur at low frequencies, to be reported and reported more quickly. Laboratories will have the cost of shipping specimens to the state laboratory.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

· Definitions (12 VAC 5-90-10):

o Hepatitis C - update the definition of acute infection and add a definition of chronic infection.

o Immunization – a new definition is proposed.

o Invasive – add a definition to clarify the use of this term on the reportable disease list.

o Laboratory - add a definition of laboratory.

o Lead – strike the requirement that the blood test has be to based on venous blood.

o Serology – add a definition for use in reporting by laboratories.

o Tuberculosis – add definitions for active disease, tubercle bacilli, tuberculosis, and tuberculin skin test and update the definition of tuberculosis infection in children age < 4 years.

o Vaccinia -- add a definition of vaccinia disease or adverse event.

· Reportable Disease List (12 VAC 5-90-80):

o In the introductory paragraph, clarify that suspected or confirmed cases are reportable, that reporting should be to the local health department, that some conditions are reportable within 24 hours and some within 3 days.

o Designate as rapidly reportable brucellosis, Q fever, smallpox, tularemia, unusual occurrence of disease of public health concern, Vibrio infection, and viral hemorrhagic fever.

o Add to the list ‘disease caused by an agent that may have been used as a weapon’, and designate it as a condition requiring rapid reporting. This is in response to a new law that went into effect this year.

o Change the hepatitis B reporting requirement to add chronic infection.

o Change tuberculosis disease to tuberculosis, active disease.

o Move the list of conditions reportable by laboratories up to this section, striking it from 12 VAC 5-90-90. See details about changes to the laboratory reporting requirement below.

o Section H – Contact Tracing. Strike the language from this section and move it under the Local Health Director section of 12 VAC 5-90-90 E. Clarify that contact tracing for tuberculosis is specifically for active tuberculosis disease.

· Those Required to Report (12 VAC 5-90-90):

o Physicians –

Change timing for reporting from 7 days to 3 days.

Note that additional elements are required to be reported by physicians for persons with confirmed or suspected active tuberculosis disease.

Strike provision allowing provider organizations to report on behalf of physicians.

Allow electronic transmission of reports when agreeable to health department and physician.

Require reporting of pregnancy status of females who test positive for HBsAg, if available.

o Directors of Laboratories –

Update the confirmatory laboratory tests for anthrax, arboviral infection, botulism, brucellosis, chancroid, cholera, cryptosporidiosis, diphtheria, E. coli, gonococcal infection, H. influenzae, hepatitis B, influenza, lead, malaria, measles, meningococcal disease, mycobacterial diseases, syphilis.

Add the following diseases and their confirmatory tests to the list of conditions reportable by laboratory directors: chickenpox, Creutzfeldt-Jakob disease, ehrlichiosis, hepatitis C, psittacosis, Q fever, Rocky Mountain spotted fever, smallpox, Streptococcus pneumoniae infection in children <5 years of age, tularemia, typhus, vaccinia, viral hemorrhagic fever, and yellow fever.

Change timing of reporting from 7 days to 3 days.

Require the reporting of pregnancy status of females who test positive for HBsAg, if available.

Require all laboratories to submit certain isolates to the state lab.

Require Shiga toxin positive stool specimens to be submitted to the state lab.

Allow electronic transmission of reports when agreeable to health department and laboratory.

o Person in charge of a medical care facility –

Change the timing of reporting from 7 days to 3 days.

Require the reporting of pregnancy status of females who test positive for HBsAg, if available.

Allow electronic transmission of reports when agreeable to health department and facility.

o Persons in charge of hospitals, nursing and other facilities (reporting disease in dead body) – Add smallpox, active tuberculosis, vaccinia, and viral hemorrhagic fever to the list of conditions about which a funeral director should be notified.

o Persons in charge of summer camps -- Require reporting of outbreaks in order to be consistent with the requirements of the Code of Virginia.

o Employees, Applicants, and Persons in Charge of Food Establishments -- Refer to the reporting requirements of the Food Regulations.

· Immunization (12 VAC 5-90-110) – Update the immunization schedule for childhood vaccines.

· Cancer Reporting (12 VAC 5-90-160 and 12 VAC 5-90-180):

o Update the definition of reportable cancers to encourage the reporting of benign nervous system tumors and exclude the reporting of carcinoma in situ of the cervix.

o Change the title of 12 VAC 5-90-180 from Data to be Reported to Report Contents and Procedures.

· Tuberculosis Control (New Section - Part X – 12 VAC 5-90-220):

o Specify additional data to be reported on persons with active TB disease by physicians, directors of medical care facilities, directors of correctional facilities, and laboratories in initial, secondary, and subsequent reports.

o Require treatment plans.
o Require reporting of various laboratory results.

· Reporting of Dangerous Microbes and Pathogens (New Section - Part XII – 12 VAC 5-90-280 through 12 VAC 5-90-360):
o Explain the procedure and requirements for the reporting of dangerous microbes and pathogens by laboratories, including reportable agents, items to report, timing of reports, those required to report, exemption from reporting, and release of reported information. This section is added in response to a new law that went into effect in 2002.

Alternatives

Please describe the specific 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.

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.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

No comments were received during the Notice of Intended Regulatory Action comment period.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The proposed amendments to the regulations have been carefully drafted to ensure that they embody the most appropriate, least burdensome and least intrusive framework for effectively administering disease reporting and control in Virginia.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The Virginia Department of Health will review the regulations each year to determine if further amendments are necessary in light of changes in the Code of Virginia or current federal recommendations regarding methods of disease reporting, disease control, and emergency preparedness.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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.

Not required, by Executive Order