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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) citation(s)	12 VAC5-90
Regulation title(s)	Regulations for Disease Reporting and Control
Action title	General Update to Reportable List and Other Reporting Details
Date this document prepared	January 17, 2018

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned 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 other details related to reporting and disease control. The Virginia Department of Health is proposing an amendment to the regulations to bring them into compliance with recent changes in the field of communicable disease detection and control and to allow greater flexibility with respect to reporting requirements in light of rapidly changing laboratory technologies and the emergence of new pathogens that are of public health concern.

The specific changes that will be proposed include: listing reportable organisms next to disease names so the reportable disease lists are equally meaningful to practicing clinicians and laboratorians; removing specific laboratory tests that are reportable for each particular laboratory-reportable condition and replacing those provisions with a statement that the laboratory will report any laboratory evidence of the condition; and adding a mechanism for the Department to maintain a list that will be updated annually and allow the surveillance of emerging conditions and special pathogens, such as newly recognized drug-

resistant infections. The health department plans to maintain a list of reportable laboratory tests and emerging conditions in guidance documents rather than in regulation, as these are subject to change and a timelier process is needed to ensure surveillance of conditions of public health concern. Additional amendments include removal of the requirement for physicians and directors of medical care facilities to submit weekly counts of cases of influenza; limitation of the reporting of select agents to only those scenarios in which such agents are released, lost, or stolen; and addition of the requirement for morbidity reporting to be done through the Department's online morbidity reporting portal.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

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 describe 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, please explain any potential issues that may need to be addressed as the regulation is developed.

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 emerging conditions and those detected through new laboratory technologies. The rapidly changing world of communicable diseases requires public health surveillance systems that are flexible and responsive to changes. The current regulations do not permit this level of flexibility. Removing detailed requirements from the regulations and maintaining them as agency guidance documents will provide the flexibility needed to respond to the occurrence of newly emerging conditions and development of laboratory technologies. 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 that are being considered, the substantive changes to existing sections that are being considered, or both.

12VAC5-90-10

- Inclusion of a definition for emerging infection or special pathogen or other means of identifying arising pathogens of concern that will be addressed in a Department document and updated annually
- Removal of “Hepatitis C, acute”, “Hepatitis C, chronic”, and “Tuberculosis” definitions

12VAC5-90-80

- Removal of “AIDS” from the reportable disease list
- Addition of organism name after condition name (e.g., Yersiniosis (Yersinia spp.)) on the reportable disease list
- Removal of specific laboratory test types that are reportable under the conditions reportable by laboratory directors and the addition of organism name after condition name on the list of conditions reportable by laboratory directors
- Addition of specific language regarding the reporting of emerging infections or special pathogens.

12VAC5-90-90

- Removal of language pertaining to the reporting of the number of influenza cases by week
- Addition of language requiring reporting via the department’s online Confidential Morbidity Report portal

12VAC5-90-280 et seq.

- Removal of most definitions
- Removal of subsection C, D, F, G, so that select agent reporting is required only if a specimen is lost, released, or stolen

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 there any that are advisable.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including 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 hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency’s contact if you’re interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Diane Woolard, Director, Division of Surveillance and Investigation, Virginia Department of Health, P.O. 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 midnight on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.