Virginia Regulatory Town Hall

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Final 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	Filing Final Regulations for Disease Reporting and Control
Document preparation date	Enter date this form is uploaded on the Town Hall

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style, and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. Do ***not*** *state each provision or amendment or restate the purpose and intent of the 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 filing final 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 final regulations include 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, the final regulations require the reporting of diseases within three days instead of seven days.

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 Virginia Board of Health approved on January 30, 2004 the final amendment to the Regulations for Disease Reporting and Control.

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, 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.

If the final text differs from the text at the proposed stage, please indicate whether the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final 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 regulations. Specifically, Section 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, as well as which dangerous microbes and pathogens are to be reported by laboratories and the method, manner and timing 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 final regulations and that it comports with applicable state and/or federal law.

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.

In response to the 2002 General Assembly amending §32.1-35 and 32.1-36 of the Code of Virginia, final regulations for Disease Reporting and Control are being filed, requiring laboratories to report their inventories and changes in inventories of dangerous microbes and pathogens to the Department of Health. Additionally, final regulations are being filed to amend

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. A more detailed discussion is required under the "All changes made in this regulatory action" section.

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 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 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 to minimize the spread of disease.

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
12 VAC 5-90-80	Report Hansen disease	'Hansen disease' to 'Hansen's disease'	Revised wording is more accurate
12 VAC 5-90-80	Report Rubella within 3 days to the local health department	Rubella designated as a condition requiring rapid communication (within 24 hours)	Rubella is highly contagious and Immediate public health actions are necessary in response to a reported case
12 VAC 5-90-80	Labs required to report Human immunodeficiency virus (HIV) infection	Updated language related to lab reporting of HIV infection	Language is consistent with common laboratory practice
12 VAC 5-90-80 H	Allows Commissioner or designee to establish temporary surveillance systems for diseases not on the reportable disease list	Struck the word 'temporary'	Special surveillance systems for bioterrorism have been in place for the past two years and will continue for the foreseeable future
12 VAC 5-90-90 B	Allows the director of a medical care facility to report information to the health department on behalf of the lab operating in the facility	Changed the word 'report' to 'notify'	Change clarifies that directors would notify the health department about reportable diseases but would not submit specimens on behalf of a laboratory operating in the facility
12 VAC 5-90-160	Reporting of benign tumors of the brain and central nervous system was encouraged	Reporting of benign tumors of the brain and central nervous system is required	The Benign Brain Tumor Cancer Registries Amendment Act (Public Law 107-260) signed into effect in Oct 2002 requires reporting of brain-related tumors beginning with cases diagnosed on or after Jan 01, 2004
12 VAC 5-90-180	All the listed data elements must be included in reports of cancer cases	Add 'when applicable' to the list of data elements required to be reported	Clarifies reporting requirements so that a laboratory or other entity that does not have access to certain data elements will be in compliance with the regulations when submitting reports
12 VAC 5-90-225.A.1	In the list of data elements to be included in tuberculosis reports, included date of birth but not age	Age was added to the list of data elements	Reporters often know age and not month and day of birth. Adding age to the list of data elements will allow age information to be reported when complete date of birth is not known
Corrected typographic errors.			

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.

Commenter	Comment	Agency response
District Epidemiologist, Southside, Virginia Department of Health (VDH)	1. Changing the timing of reporting from 7 days to 3 days would be challenging but more appropriate 2. 'Tuberculosis, active disease', instead of 'Tuberculosis Disease' is more appropriate	Comments supportive. No action required.
District Epidemiologist, Arlington, VDH	Rubella should require rapid communication because it is contagious; infectious before symptom onset;	Rubella designated as condition requiring rapid

	uncommon; requires more vigilant surveillance; and immediate follow up of pregnant contacts is needed.	communication
Virginia Cancer Registry Director and staff, VDH	The Benign Brain Tumor Cancer Registries Act (Public Law 107-260) requires reporting of brain-related tumors beginning with cases diagnosed on or after Jan 1, 2004	Benign brain and central nervous system tumors made reportable conditions
Senior Epidemiologist, VDH	In 12 VAC 5-90-80, section H, remove the word 'temporary' in Line 5 since some syndromic systems have been in place since Sep 12, 2001, and will continue for the foreseeable future	Struck the word 'temporary'
Hospital Infection Control Practitioner (ICP), Henrico County	Three day reporting requirement is a concern because by the time the hospital gets the reports through the mail, it will not meet the guidelines. It might help if the form could be put online. If information is sent electronically, getting an instant confirmation would be helpful.	The person submitting the comments was telephoned. She understands the need for timely reporting and currently reports in less than 3 days now, so changing the requirement from 7 days to 3 days will not change her usual practice.
Hospital ICP, Henrico County	Typo in section 12 VAC 5-90-80 C of 'Momkeypox'	Changed 'Momkeypox' to 'Monkeypox'
Hospital ICP, Henrico County	There is nothing of major concern, other than the 3 day reporting requirement. The reporting of active tuberculosis cases in-hospital within 24 hours is possibly an issue. If the patient is appropriately isolated and workup and treatment is in progress, it doesn't seem urgent to report.	The person submitting the comments was telephoned. She reports in less than 3 days now, so the change would not affect her usual practice. The rapid reporting of active tuberculosis is important so that VDH can start the investigation of contacts outside the hospital as soon as possible.
Hospital ICP, rural hospital in Eastern Region	Sending out specimens to a reference lab increases turnaround time in obtaining results, so complying with the 3 day reporting requirement would be hard. Favor a list of immediate notifications with the usual 7 day reporting of all results. Reporting of chronic findings previously reported should be excluded from repeat reporting.	The person submitting the comments was telephoned. Changing the reporting requirement to 3 days would not alter her current practice. Repeat reporting of chronic findings is necessary to ensure data are up-to-date. May be revisited later if practice is determined to be wasteful.
Large private reference laboratory	1. Laboratory would have to bear the burden of the cost of shipping 12 additional types of cultures to the state laboratory, at $9-12 per specimen, which is onerous and an unfair burden for all laboratories. Laboratory proposes that the state provide postage-paid mailing envelopes for the submission of such specimens. 2. Reporting will not be possible on hepatitis C and paired sera unless multi-test specimens are submitted on the same accession. 3. Lab can only provide data fields that the ordering provider supplies. Suggest adding at the end of	1. The laboratory's courier system could drop specimens at a hospital, where the DCLS courier could pick them up and send them to the state lab at no cost. 2, 3. We acknowledge that labs can only report information to which they have access but want to encourage them to

	the sentence that states that each report shall contain the specific data items the phrase 'when provided to the laboratory by the ordering provider'. 4. Recommend adding to the statement that says that a laboratory must report results run in-house or referred to an out-of-state laboratory that says 'unless there is an agreement between the referring laboratory and the out-of-state laboratory that complete reporting will be performed by the referring laboratory'. 5. Rather than requiring HIV EIA testing 'in duplicate at the same time or singly at different times', require that the EIA test be performed as a single test and, if positive, the EIA test be performed again; then, positive tests would be confirmed with a confirmatory test by a different methodology. Duplicate testing is not required in the FDA-approved package insert or as a recommendation by the CDC or NCCLS. 6. Pathology reference laboratory may not have all data elements available to them that are required for reporting to the Virginia Cancer Registry, such as sequence numbers, stage, and treatment. Recommend adding 'when applicable' to the entire list of data elements.	ensure information needed for public health is reported to the extent possible. 4. This needs more thought, discussion, and input before it could be implemented. Enforcement of out-of-state laboratory practices is limited. Will consider this the next time the regulations are amended. 5, 6. Changes made
Medical Epidemiologist, VDH	1. Reportable disease definition defines all illnesses but does not finish the thought about reportability. Suggest adding 'and declared by the Board of Health to require notification to public health' 2. In the definition of 'Tuberculosis, active disease' change 'airborne microorganism' to 'tubercle bacilli' 3. Check on Hansen disease vs. Hansen's disease as the proper new term for leprosy 4. In the lab list a carriage return occurs in the middle of the Chlamydia trachomatis section; extra unnecessary right parenthesis at the end of HIV infection; extra space before SARS; vaccinia listed twice, use the second option and add ', or culture'; on vancomycin-resistant Staph the font changes on 'culture'; monkeypox misspelled; need comma between Listeria and meningococcal in list of specimens to be submitted to DCLS. 5. SARS should be on the list of rapidly reportable conditions in section C on page 3705 6. Section C on page 3707, do persons in charge of a medical facility have to report each admission for a reportable condition? 7. Section F on page 3708, should funeral homes be notified of cholera and SARS? 8. Part X, TB control, item A.1, should date of birth and age be reported instead of just date of birth?	1. The definition ends with 'as determined by the board', so this is already covered 2. The term 'airborne' is needed to tie in to the involuntary confinement part of the Code and its use is consistent with the Code. No change made. 3. Change made 4. Changes made 5. Change made 6. No change made 7. No change made 8. Added age to be consistent with other sections

Community hospital in Southwest Virginia	1. Regarding the requirement to report the pregnancy status of females positive for HBsAg, would the lab be required to contact the physician to determine the pregnancy status? 2. What does 'if available' mean in terms of reporting? 3. Changes clarify the regulations and enable those required to report to do so in a timely and inclusive manner.	1. No change made. Lab not required to determine pregnancy status. VDH does that by writing physicians. 2. 'If available' means that the information has to be reported only if it is known to the reporting source at the time the report is made. 3. Positive comment. No change needed.
Infectious disease physician in Northern Virginia	1. Requirement for labs to submit certain isolates to the health department is open-ended and seems unilateral. 2. Changing the timing of reporting from 7 days to 3 – workload of the laboratory is stressed and rationale is not provided. A compromise of 5 days may be reasonable. 3, 4, 5. Applaud changes in language pertaining to tuberculosis, upgrading of hepatitis B definitions, and inclusion of organisms such as cyclosporiasis and monkeypox. 6. Deletion of paragraph on contact tracing seems to be replaced on another page. This seems minor and acceptable. 7. Important upgrade in language to include assisted living facilities. 8. Question the deletion of benign brain tumors. They grow in such a way as to be implicitly malignant in physiology.	1. This comment was based on the summary of the proposed change. Clarifying language exists later in the regulation and no change is needed. 2. VDH is expected to be aware of the health status of Virginians. Labs have flexibility in means of reporting. Should be able to generate report (e.g., printout) in three days. 3, 4, 5, 6, 7. Positive comments. No changes needed. 8. Requirement to report benign brain tumors was added back in
Surveillance Coordinator, VDH	Laboratory reporting involves notifying the health department and sometimes also submitting specimens to the state lab. In 12-VAC 5-90-90 B, the director of the medical care facility can assume the responsibility for the notification part of the reporting requirement but not the submitting part.	Change made to substitute 'notify' for 'report to'

Enter any other statement here

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
12 VAC 5-90-10		The changes update existing definitions and/or add needed new ones.	Changes update definitions and bring them into agreement with current public health practices. 1. Hepatitis C - update acute infection and add chronic infection definitions. 2. Immunization – a new definition is proposed. 3. Invasive – add a definition to clarify the use of this term on the reportable disease list. 4. Laboratory-- add a definition of laboratory. 5. Lead – strike the requirement that the blood test has be to based on venous blood. 6. Serology – add a definition for use in reporting by laboratories. 7. Tuberculosis – add definitions for active disease, tubercle bacilli, tuberculosis, and tuberculin skin test and update definition of infection in children age < 4 years. 8. Vaccinia-- add a definition of vaccinia disease or adverse event.
12 VAC 5-90-80	6. 12 VAC 5-90-90 E	1. Some conditions are currently reportable within 24 hours and some within 7 days 2. Reportable within 7 days 3. Not currently reportable 4. Not currently reportable except in the case of pregnant women who are HBsAg positive 5. Report tuberculosis disease 6. Currently reportable under provisions of emergency regulation 7. Conditions and lab tests are reportable, but the list is not current 8. Conduct contact tracing	1. In the introductory paragraph, clarify that suspected or confirmed cases are reportable, reporting should be to the local health department, some conditions are reportable within 24 hours and some within 3 days. 2. Designate as rapidly reportable brucellosis, monkeypox, Q fever, rubella, SARS, smallpox, tularemia, unusual occurrence of disease of public health concern, vaccinia, Vibrio infection, and viral hemorrhagic fever, due to need to implement public health actions immediately. 3. 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 mandate in the Code of Virginia 4. Change the hepatitis B reporting requirement to add chronic infection 5. Change ‘tuberculosis disease’ to ‘tuberculosis, active disease’ for clarity 6. Add monkeypox, SARS, vaccinia as a final regulatory action to finalize actions taken as emergency regulation in 2003 7. Add the list of conditions reportable by laboratories to this section, removing it from 12 VAC 5-90-90. Also update the list of reportable conditions for laboratories as well as the tests conducted to verify diagnoses 8. Section H – Contact Tracing. Strike 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.
12 VAC 5-90-90		Physicians: 1. Report within 7 days 2. Report tuberculosis disease to the health department 3. Provider organizations may report on behalf of physicians 4. Not specifically cited in regulations 5. HBsAg positive is reportable in pregnant women but pregnancy status of all women with positive HBsAg is not reportable	Physicians: 1. Change reporting requirement from 7 days to 3 days to improve timeliness 2. Note that additional elements are required to be reported by physicians for persons with confirmed or suspected active tuberculosis disease 3. Strike provision allowing provider organizations to report on behalf of physicians 4. Allow electronic transmission of reports when agreeable to health department and physician 5. Require reporting of pregnancy status of females who test positive for HBsAg, if available
	Directors of laboratories 12 VAC 5-90-80	Directors of laboratories: 1. Report listed conditions 2. Diseases are currently reportable. Changes clarify which tests are considered confirmatory. 3. Not reportable by labs 4. Report within 7 days 5. HBsAg positive is reportable in pregnant women but pregnancy status of all women with positive HBsAg is not reportable 6. HIV reportable by current definition 7. Isolates for 13 diseases are required to be submitted to state lab by hospitals 8. *E. Coli* 0157:H7 isolates are required to be submitted to state lab 9. Not specifically cited in regulations	Directors of laboratories: 1. Move the list of conditions reportable by laboratories to 12 VAC 5-90-80, striking it from 12 VAC 5-90-90 2. 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 3. 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. 4. Change reporting requirement from 7 days to 3 days to improve timeliness 5. Require the reporting of pregnancy status of females who test positive for HBsAg, if available 6. HIV reportable by updated definition, which does not require two ELISAs prior to supplemental test confirmation 7. Require all laboratories to submit 14 different isolates to the state lab for confirmation of agent and other studies 8. Require E. coli isolates and any Shiga toxin positive stool specimens to be submitted to the state lab 9. Allow electronic transmission of reports when agreeable to health department and laboratory

		Persons in charge of a medical care facility: 1. Report within 7 days 2. HBsAg positive is reportable in pregnant women but pregnancy status of all women with positive HBsAg is not reportable 3. Not specifically cited in regulations	Persons in charge of a medical care facility: 1. Change reporting requirement from 7 days to 3 days to improve timeliness 2. Require the reporting of pregnancy status of females who test positive for HBsAg, if available 3. Allow electronic transmission of reports when agreeable to health department and facility
		Persons in charge of summer camps: not specifically cited in regulations	Persons in charge of summer camps: Require reporting of outbreaks in order to be consistent with the requirements of the Code of Virginia
		Persons in charge of hospitals, nursing and other facilities (reporting disease in dead body): Report Creutzfeldt-Jakob disease, HIV, Hepatitis B, Hepatitis C, Rabies, and infectious syphilis.	Persons in charge of hospitals, nursing and other facilities (reporting disease in dead body): Add monkeypox, smallpox, active tuberculosis, vaccinia, and viral hemorrhagic fever to the list of conditions about which a funeral director should be notified so that appropriate precautions can be taken.
		Employees, Applicants, and Persons in Charge of Food Establishments: not specifically cited in regulations	Employees, Applicants, and Persons in Charge of Food Establishments: Refer to the reporting requirements of the Food Regulations
12 VAC 5-90-110		Outdated immunization schedule listed	Update the immunization schedule for childhood vaccines so that it reflects current recommendations
12 VAC 5-90-160 and 5-90-180		Benign brain tumors and carcinoma in situ of the cervix are currently reportable	1. Update definition of reportable cancers to include reporting of benign brain and central nervous system tumors and exclude reporting of carcinoma in situ of cervix. 2. Change the title of 12 VAC 5-90-180 from 'Data to be Reported' to 'Report Contents and Procedures' for clarity. 3. Add 'when applicable' to the list of data elements so pathology laboratories can be in compliance when they do not have access to currently required data elements
12 VAC 5-90-225		1. Tuberculosis disease is reportable 2. Treatment plans not required 3. Tuberculosis disease reportable; infection in children age<4 years	1. Specify additional data to be reported on persons with active tuberculosis disease by physicians, directors of medical care facilities, directors of correctional facilities, and labs in initial, secondary, and subsequent reports. 2. Require treatment plans 3. Require reporting of various lab results

		reportable	
12 VAC 5-90-280 through 12 VAC 5-90-360		Not currently reportable	Explain procedures and requirements for reporting of dangerous microbes and pathogens by labs, 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 mandate in the Code of Virginia.

Enter any other statement here

Impact on family

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

Not required, by Executive Order