

**State of Board of Health
Agenda
December 3, 2015 – 9:00 a.m.
Perimeter Center – Boardroom 2
9960 Mayland Drive
Richmond, Virginia 23233**

Call to Order and Welcome	Bruce Edwards, Chair
Pledge of Allegiance	Megan Getter
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of September 17, 2015 Minutes	Mr. Edwards
Commissioner’s Report	Marissa J. Levine, MD, MPH, FAAFP State Health Commissioner
Abortion Facility Licensure Status Report	Erik Bodin, Director Office of Licensure and Certification
Regulatory Action Update	Mr. Hilbert
Public Comment Period	
Break	
<u>Regulatory Action Items</u>	
Regulations for the Licensure of Nursing Facilities 12VAC5-371 (Fast Track Amendments)	Mr. Bodin
Regulations for the Licensure of Hospitals in Virginia 12VAC5-410 (Fast Track Amendments)	Mr. Bodin
Working Lunch	

Topic: End-of-Life Issues

Speakers: Jim Beckner, Deborah Love and Robin Cummings; Richmond Academy of Medicine

Regulatory Action Items

Regulations for Disease Reporting and Control
12VAC5-90
(Final Amendments)
(Update disease reporting – blood lead)

Laurie Forlano, DO, MPH, Director
Office of Epidemiology

Regulations for Disease Reporting and Control
12VAC5-90
(Final Amendments)
(Changes in public health practices)

Dr. Forlano

Member Reports

Other Business

Adjourn



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: November 3, 2015

TO: Virginia State Board of Health

FROM: Erik Bodin
Director, Office of Licensure and Certification

SUBJECT: Fast Track Amendments – Regulations for the Licensure of Nursing Facilities

Enclosed for your review is a Fast Track action to amend the Regulations for the Licensure of Nursing Facilities (12VAC5-371) to reflect the requirements of House Bill 2130 enacted by the 2013 General Assembly.

HB 2130 (2013) mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes and requires that the Board utilize existing policies and procedures set forth in the Board's 2004 Guideline "Electronic Monitoring of Residents' Rooms" in the promulgation of the regulations. This regulatory action shall codify the 2004 guideline which was developed to assist facilities with the privacy issues that may arise when installing electronic monitoring equipment. Installing such equipment is not mandatory; however, if installed, facilities must safeguard resident's autonomy and rights according to current federal and state privacy laws and regulations. This regulatory action provides the framework to address policies and procedures, informed consent, admission, discharge or transfer. The regulation includes the equipment request process and notice procedures, retention and ownership of tapes or recordings, and reporting suspected abuse, neglect, accident or injury discovered through electronic monitoring.

The Board of Health is requested to approve this Fast Track action at its December 2015 meeting. Should the Board of Health approve the Fast Track Action the proposed amendments will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the proposed regulations will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30 day public comment period will begin. Fifteen days after the close of the public comment period the Regulations will become effective.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-371
Regulation title(s)	Regulations for the Licensure of Nursing Facilities
Action title	Amend regulations to address implementation of voluntary electronic monitoring
Date this document prepared	September 22, 2015

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*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) 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.

House Bill 2130 enacted by the 2013 General Assembly mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. HB2130 (2013) requires that the Board utilize existing policies and procedures set forth in the Board's 2004 Guideline "Electronic Monitoring of Residents' Rooms" in the promulgation of the regulations. This proposed Fast Track action shall codify the 2004 guideline which was developed to assist facilities with the privacy issues that may arise when installing electronic monitoring equipment. Installing such equipment is not mandatory; however, if installed, facilities must safeguard resident's autonomy and rights according to current federal and state privacy laws and regulations. This regulatory action provides the framework to address policies and procedures, informed consent, admission, discharge or transfer. The regulation includes the equipment request process and notice procedures,

retention and ownership of tapes or recordings, and reporting suspected abuse, neglect, accident or injury discovered through electronic monitoring.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

The acronyms that appear in this document are as follows:

OLC means the Office of Licensure and Certification

VDH means the Virginia Department of Health

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 these amendments to the Regulations for the Licensure of Nursing Facilities on _____.

Legal basis

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

House Bill 2130 enacted by the 2013 General Assembly mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. HB2130 (2013) requires that the Board utilize existing policies and procedures set forth in the Board's 2004 Guideline "Electronic Monitoring of Residents' Rooms" in the promulgation of the regulations. Therefore, this regulatory action is mandated by law.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.

House Bill 2130 enacted by the 2013 General Assembly mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. HB2130 (2013) requires that the Board utilize existing policies and procedures set forth in

the Board's 2004 Guideline "Electronic Monitoring of Residents' Rooms" in the promulgation of the regulations. This proposed Fast Track action shall codify the 2004 guideline which was developed to assist facilities with the privacy issues that may arise when installing electronic monitoring equipment. Installing such equipment is not mandatory; however, if installed, facilities must safeguard resident's autonomy and rights according to current federal and state privacy laws and regulations. This regulatory action provides the framework to address policies and procedures, informed consent, admission, discharge or transfer. The regulation includes the equipment request process and notice procedures, retention and ownership of tapes or recordings, and reporting suspected abuse, neglect, accident or injury discovered through electronic monitoring. The regulation will protect and promote public health, safety and welfare of citizens through the establishment of a framework which would set standards regarding electronic monitoring in nursing facility resident rooms. This framework will ensure that resident privacy and autonomy is paramount when electronic monitoring is utilized.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

HB 2130 (2013) mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. HB2130 (2013) requires that the Board utilize existing policies and procedures set forth in the Board's 2004 Guideline "Electronic Monitoring of Residents' Rooms" in the promulgation of the regulations. The guideline was developed with the assistance and input of the Virginia State Police to accurately reflect state and federal privacy laws. As a result, the guideline has been widely used and has not necessitated update since its implementation. Therefore, VDH believes the proposed regulation will be noncontroversial, allowing use of the fast-track process.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

Electronic monitoring in resident rooms - Provides the framework for policies and procedures, informed consent, right of implementation/refusal, retention of tapes and recordings, and reporting of abuse, neglect, accident or injury discovered via electronic monitoring.

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 advantages of the regulatory action to the public are increased safety of nursing facility patients. There are no known disadvantages to the public. The primary advantages to the Agency and the

Commonwealth are increased care and safety for citizens throughout the Commonwealth who chose to utilize electronic monitoring. There are no known disadvantages to the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is 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.

There are no requirements in this proposal that exceed 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.

No locality will be particularly affected by the proposed regulatory action.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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.

HB 2130 (2013) mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. HB2130 (2013) requires that the Board utilize existing policies and procedures set forth in the Board's 2004 Guideline "Electronic Monitoring of Residents' Rooms" in the promulgation of the regulations. The regulations are mandated by law and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes mandated by HB2130 (2013).

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

<p>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</p>	<p>None</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>None</p>
<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>The 286 licensed nursing facilities within the Commonwealth of Virginia, patients or residents of those facilities and their family members or legal representatives.</p>
<p>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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>All licensed nursing facilities within the Commonwealth of Virginia must comply with 12VAC5-371. A majority of the licensed nursing facilities within the Commonwealth of Virginia qualify as small businesses.</p>
<p>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>None, there are no costs unless the facility receives a request to install equipment. The regulation provides that such costs can be charged to the family, patient or resident seeking implementation of the electronic monitoring. Those individuals (patients, residents, family members) who wish to avail themselves of electronic monitoring will have a cost.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Provides the controls necessary to assure that resident autonomy and rights to personal privacy are not violated.</p>

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.

HB 2130 (2013) mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. HB2130 (2013) requires that the Board utilize existing policies and procedures set forth in the Board's 2004 Guideline "Electronic Monitoring of Residents' Rooms" in the promulgation of the regulations. The regulations are mandated by law and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes mandated by HB2130 (2013).

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of this 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.

VDH anticipates the regulations will strengthen the family and family stability through increased involvement in nursing home resident’s care and greater assurance for family members that residents are being well cared for.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre-emergency** regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
	191- <u>Electronic monitoring in resident rooms.</u>	N/A	<p><u>A. All requests for electronic monitoring shall be made in writing and signed by the resident or the resident’s legal representative, if the resident has been properly assessed incapable of requesting and authorizing the monitoring.</u></p> <p><u>B. Only authorized electronic monitoring is permitted.</u></p> <p><u>C. A facility shall not refuse to admit an individual and shall not discharge a</u></p>

			<p><u>resident due to a request to conduct authorized electronic monitoring.</u></p> <p><u>D. Family members cannot obtain electronic monitoring over the objections of the resident or the resident's roommate. No equipment may be installed pursuant to 12VAC5-371-191 (Q) over the objections of the resident or the resident's roommate. Facilities shall not use monitoring equipment in violation of the law based solely on a family member's request or approval.</u></p> <p><u>E. Authorization for electronic monitoring shall be kept in the resident's medical record.</u></p> <p><u>F. Facilities shall designate one staff person to be responsible for handling monitoring requests, and to coordinate the installation, operation, and dismantling of all equipment.</u></p> <p><u>G. Facilities may designate custodial ownership of any recordings from monitoring devices to the resident's family. Facility retained recordings shall be considered part of the resident's medical record. All state and federal regulations pertaining to medical records apply to monitoring tapes retained by a facility.</u></p> <p><u>H. If a facility chooses to retain ownership of recordings, the facility shall not permit viewings of recordings without the resident's approval. Should a resident approve viewing, the facility shall accommodate family viewing of any recordings, including, but not limited to:</u></p> <ol style="list-style-type: none"> <u>1. Providing appropriate playing/viewing equipment;</u> <u>2. Privacy during viewing; and</u> <u>3. Viewing times convenient to the family.</u> <p><u>I. Any incidences regarding safety or quality of care discovered as a result of viewing a recording shall be reported immediately to the facility administrator and to the OLC. Facilities shall instruct family members of this reporting requirement and shall provide family members with the OLC's Complaint Hotline telephone number.</u></p> <p><u>J. A facility shall have no obligation to seek access to a tape in its possession or to have knowledge of a tape's content,</u></p>
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			<p><u>unless the facility is aware of a taped incident of suspected abuse, neglect, accident or injury; or the resident or the resident's legal representative, or a government agency, seeks to use a tape in any way that affects the facility. Facilities shall immediately report suspected abuse and neglect, discovered as a result of using monitoring devices, as required by law.</u></p> <p><u>K. A facility may require the resident, the resident's family, or legal representative to be responsible for all aspects of the operation of the monitoring equipment, including the removal and replacement of tapes, and for firewall protections to prevent images that would violate obscenity laws from being inadvertently shown on the Internet.</u></p> <p><u>L. Facility staff shall not refuse to enter a monitored room.</u></p> <p><u>M. Any electronic monitoring equipment shall be installed in a manner that is safe for residents, employees, or visitors who may be moving about the resident's room.</u></p> <p><u>N. A facility shall make reasonable physical accommodation for monitoring equipment including:</u></p> <ol style="list-style-type: none"> <u>1. Providing a reasonably secure place to mount the device; and</u> <u>2. Providing access to power sources for the device.</u> <p><u>O. A facility may require a resident, or a resident's legal representative, to pay for all costs, other than the cost of electricity, associated with installing electronic monitoring equipment. Such costs shall be reasonable and may include, but are not limited to: equipment, tapes and installation, compliance with life safety and building/electrical codes, maintenance or removal of the equipment, posting and removal of any public notices, or structural repairs to the building resulting from the removal of the equipment. Facilities shall give 45 days notice of an increase in monthly monitoring fees.</u></p> <p><u>P. Any equipment installed for the purpose of monitoring a resident room shall be fixed and unable to rotate.</u></p> <p><u>Q. The informed consent of all</u></p>
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			<p><u>residents assigned to the monitoring room shall be obtained prior to any electronic monitoring equipment being installed.</u></p> <p><u>R. A facility may require that the resident, or the resident's legal representative, obtain the necessary signed consent of other residents in the room.</u></p> <p><u>S. A copy of any signed consent form shall be kept in the resident's medical record as well as on file with the facility's designated electronic monitoring coordinator.</u></p> <p><u>T. Any resident of a monitored room may condition his or her consent for use of monitoring devices. Such conditions may be, but are not limited to, pointing the camera away or limiting or prohibiting the use of certain devices. If conditions are placed on consent, then electronic monitoring shall be conducted according to those conditions.</u></p> <p><u>U. The facility shall conspicuously post and maintain a notice at the entrance to the resident's room stating that an electronic monitoring device is in operation.</u></p> <p><u>V. Facilities shall notify all staff and their VDH OLC Long Term Care Supervisor that electronic monitoring is in use.</u></p> <p><u>W. Covert monitoring is prohibited. However, a facility shall not discharge a resident from a facility because covert electronic monitoring was conducted by or on behalf of a resident.</u></p> <p><u>X. If covert monitoring is discovered, the facility may require a resident, or the resident's legal representative, to meet all the requirements for authorized monitoring prior to the continuation of monitoring.</u></p> <p><u>Y. Each nursing facility shall adopt policies and procedures for electronic monitoring. These policies and procedures shall address all the elements of this section, 12VAC5-371-191.</u></p> <p>Intent: Providing assurance that a resident's dignity and right to personal, bodily privacy and autonomy are not violated should electronic monitoring be implemented within their room with their</p>
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			<p>consent. These provisions already exist in a Guidance document published by VDH OLC, the Department is simply placing those provisions into the regulations as required by HB2130 (2013).</p> <p>Likely impact: Greater patient safety, more comprehensive regulations.</p>
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1 Project 4519 - none

2 DEPARTMENT OF HEALTH

3 CH371- Amend regulations related to electronic monitoring

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5 **12VAC5-371-191. Electronic monitoring in resident rooms.**

6 A. All requests for electronic monitoring shall be made in writing and signed by the resident
7 or the resident's legal representative, if the resident has been properly assessed incapable of
8 requesting and authorizing the monitoring.

9 B. Only authorized electronic monitoring is permitted.

10 C. A facility shall not refuse to admit an individual and shall not discharge a resident due to a
11 request to conduct authorized electronic monitoring.

12 D. Family members cannot obtain electronic monitoring over the objections of the resident or
13 the resident's roommate. No equipment may be installed pursuant to 12VAC5-371-191 (Q) over
14 the objections of the resident or the resident's roommate. Facilities shall not use monitoring
15 equipment in violation of the law based solely on a family member's request or approval.

16 E. Authorization for electronic monitoring shall be kept in the resident's medical record.

17 F. Facilities shall designate one staff person to be responsible for handling monitoring
18 requests, and to coordinate the installation, operation, and dismantling of all equipment.

19 G. Facilities may designate custodial ownership of any recordings from monitoring devices
20 to the resident's family. Facility retained recordings shall be considered part of the resident's
21 medical record. All state and federal regulations pertaining to medical records apply to
22 monitoring tapes retained by a facility.

23 H. If a facility chooses to retain ownership of recordings, the facility shall not permit viewings
24 of recordings without the resident's approval. Should a resident approve viewing, the facility
25 shall accommodate family viewing of any recordings, including, but not limited to:

26 1. Providing appropriate playing/viewing equipment;

27 2. Privacy during viewing; and

28 3. Viewing times convenient to the family.

29 I. Any incidences regarding safety or quality of care discovered as a result of viewing a
30 recording shall be reported immediately to the facility administrator and to the OLC. Facilities
31 shall instruct family members of this reporting requirement and shall provide family members
32 with the OLC's Complaint Hotline telephone number.

33 J. A facility shall have no obligation to seek access to a tape in its possession or to have
34 knowledge of a tape's content, unless the facility is aware of a taped incident of suspected
35 abuse, neglect, accident or injury; or the resident or the resident's legal representative, or a
36 government agency, seeks to use a tape in any way that affects the facility. Facilities shall
37 immediately report suspected abuse and neglect, discovered as a result of using monitoring
38 devices, as required by law.

39 K. A facility may require the resident, the resident's family, or legal representative to be
40 responsible for all aspects of the operation of the monitoring equipment, including the removal
41 and replacement of tapes, and for firewall protections to prevent images that would violate
42 obscenity laws from being inadvertently shown on the Internet.

43 L. Facility staff shall not refuse to enter a monitored room.

44 M. Any electronic monitoring equipment shall be installed in a manner that is safe for
45 residents, employees, or visitors who may be moving about the resident's room.

1 N. A facility shall make reasonable physical accommodation for monitoring equipment
2 including:
3 1. Providing a reasonably secure place to mount the device; and
4 2. Providing access to power sources for the device.
5 O. A facility may require a resident, or a resident's legal representative, to pay for all costs,
6 other than the cost of electricity, associated with installing electronic monitoring equipment.
7 Such costs shall be reasonable and may include, but are not limited to: equipment, tapes and
8 installation, compliance with life safety and building/electrical codes, maintenance or removal of
9 the equipment, posting and removal of any public notices, or structural repairs to the building
10 resulting from the removal of the equipment. Facilities shall give 45 days notice of an increase in
11 monthly monitoring fees.
12 P. Any equipment installed for the purpose of monitoring a resident room shall be fixed and
13 unable to rotate.
14 Q. The informed consent of all residents assigned to the monitoring room shall be obtained
15 prior to any electronic monitoring equipment being installed.
16 R. A facility may require that the resident, or the resident's legal representative, obtain the
17 necessary signed consent of other residents in the room.
18 S. A copy of any signed consent form shall be kept in the resident's medical record as well
19 as on file with the facility's designated electronic monitoring coordinator.
20 T. Any resident of a monitored room may condition his or her consent for use of monitoring
21 devices. Such conditions may be, but are not limited to, pointing the camera away or limiting or
22 prohibiting the use of certain devices. If conditions are placed on consent, then electronic
23 monitoring shall be conducted according to those conditions.
24 U. The facility shall conspicuously post and maintain a notice at the entrance to the
25 resident's room stating that an electronic monitoring device is in operation.
26 V. Facilities shall notify all staff and their VDH OLC Long Term Care Supervisor that
27 electronic monitoring is in use.
28 W. Covert monitoring is prohibited. However, a facility shall not discharge a resident from a
29 facility because covert electronic monitoring was conducted by or on behalf of a resident.
30 X. If covert monitoring is discovered, the facility may require a resident, or the resident's
31 legal representative, to meet all the requirements for authorized monitoring prior to the
32 continuation of monitoring.
33 Y. Each nursing facility shall adopt policies and procedures for electronic monitoring. These
34 policies and procedures shall address all the elements of this section, 12VAC5-371-191.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: November 3, 2015

TO: Virginia State Board of Health

FROM: Erik Bodin
Director, Office of Licensure and Certification

SUBJECT: Fast Track Amendments- Regulations for the Licensure of Hospitals in Virginia

Enclosed for your review is a Fast Track action to amend the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410) to reflect changes to federal regulations.

The Center for Medicare and Medicaid Services (CMS) revised 42 C.F.R. § 482.22 (b) in 2014 to add § 482.22 (b) (4) which permits a hospital that is part of a hospital system consisting of multiple, separately certificated hospitals to participate in a unified, integrated medical staff that the hospital system utilizes for two or more of its member hospitals, in accordance with state law. The Regulations for the Licensure of Hospitals in Virginia is currently written in a manner that can be interpreted to be more restrictive than the federal regulations. This was not the intent and therefore this Fast Track action is presented to amend the regulations to remove restrictions that may be interpreted to be more stringent than federal law.

The Board of Health is requested to approve this Fast Track action at its December 2015 meeting. Should the Board of Health approve the Fast Track Action the proposed amendments will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the proposed regulations will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30 day public comment period will begin. Fifteen days after the close of the public comment period the Regulations will become effective.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-410
Regulation title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Update the Regulations to reflect a CMS issued final rule enabling hospitals that are part of a hospital system to have a unified integrated medical staff
Date this document prepared	September 24, 2015

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*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) 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.

The State Board of Health (Board) proposes to amend 12VAC5-410 et. seq. Regulations for the Licensure of Hospitals in Virginia to reflect changes to federal regulations. The Center for Medicare and Medicaid Services (CMS) revised 42 C.F.R. § 482.22 (b) in 2014 to add § 482.22 (b)(4) which permits a hospital that is part of a hospital system consisting of multiple, separately certificated hospitals to participate in a unified, integrated medical staff that the hospital system utilizes for two or more of its member hospitals, in accordance with state law. The Regulations for the Licensure of Hospitals in Virginia is currently written in a manner that can be interpreted to be more restrictive than the federal regulations. This was not the intent and therefore this regulatory action will amend the regulations to remove restrictions that may be interpreted to be more stringent than federal law.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

CMS means the Centers for Medicare and Medicaid Services

OLC means the Office of Licensure and Certification

VDH means the Virginia Department of Health

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.

These amendments to the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410) were approved by the State Board of Health on _____.

Legal basis

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

The regulation is promulgated under the authority of §§ 32.1-12 and 32.1-127 of Chapter 5 of Title 32.1 of the Code of Virginia (Code). Section 32.1-12 grants the board the legal authority "to make, adopt, promulgate, and enforce such regulations necessary to carry out the provisions of Title 32.1 of the Code." Section 32.1-127 of the Code of Virginia directs the Board to promulgate regulations with minimum standards for the construction and maintenance of hospitals, the operation, staffing and equipping of hospitals, qualifications and training of staff of hospitals, conditions under which a hospital may provide medical and nursing services to patients in their places of residence and policies related to infection prevention, disaster preparedness and facility security.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.

The Center for Medicare and Medicaid Services (CMS) revised 42 C.F.R. § 482.22 (b) in 2014 to add § 482.22 (b)(4) which permits a hospital that is part of a hospital system consisting of multiple, separately certificated hospitals to participate in a unified, integrated medical staff that the hospital system utilizes for

two or more of its member hospitals, in accordance with state law. The Regulations for the Licensure of Hospitals in Virginia is currently written in a manner that can be interpreted to be more restrictive than the federal regulations. This was not the intent and therefore this regulatory action will amend the regulations to remove restrictions that may be interpreted to be more stringent than federal law. This regulatory action will protect the health and welfare of Virginians by ensuring that patients within a hospital setting benefit from the improved efficiency, quality and patient safety made possible through a unified, integrated medical staff.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

These amendments simply ensure that the Commonwealth’s regulations are not more restrictive than federal regulations. These amendments have also been prepared with input from stakeholders. Therefore, the Department does not expect that this regulatory action will be controversial.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the “Detail of changes” section below.

12VAC5-410-210. Clarify the requirement that each hospital have an organized medical staff. Add language which allows hospitals which are a part of a hospital system to have a unified and integrated medical staff. Add subsections to specify the requirements of unified and integrated medical staffs.

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 the agency, the Commonwealth and the public of the proposed regulatory action will be less burdensome regulations. The proposed regulatory action will also lead to improved efficiency, quality and patient safety created through unified and integrated medical staffs. There are no known disadvantages to the agency, the Commonwealth or the public.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is 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.

There are no requirements in this proposal that exceed 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.

No locality will be particularly affected by the proposed regulatory action.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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.

The alternative regulatory methods are not applicable. The regulations are required by the Code and the proposed amendments are attempting to reduce the burden of the existing requirements.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

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	None
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Those individuals who serve as the medical staff to hospitals throughout the Commonwealth. Patients served by hospitals throughout the Commonwealth.
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: a) is independently owned and operated and;	There are 106 licensed hospitals and critical access hospitals within the Commonwealth.

b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	No projected cost.
Beneficial impact the regulation is designed to produce.	Less burdensome nature of the regulations.

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.

There are no other viable alternatives other than the proposed amendments to obtain the objectives of the board.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of this 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 board has assessed the impact the proposed amendments will have on the institution of the family and family stability. The board anticipates no impact to the family or family stability.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre-emergency** regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-410-210		<p>A. Each hospital shall have an organized medical staff responsible to the governing body of the hospital for its own organized governance and all medical care provided to patients.</p> <p>B. The medical staff shall be responsible to the hospital governing board and maintain appropriate standards of professional performance through staff appointment criteria, delineation of staff privileges, continuing peer review and other appropriate mechanisms.</p> <p>C. The medical staff, subject to approval by the governing body, shall develop bylaws incorporating details of the medical staff organization and governance, giving effect to its general powers, duties, and responsibilities including:</p> <ol style="list-style-type: none"> 1. Methods of selection, election, or appointment of all officers and other executive committee members and officers; 2. Provisions for the selection and appointment of officers of departments or services specifying required qualifications; 	<p>A. Each hospital shall have an organized medical staff responsible to the governing body of the hospital for its own organized governance and all medical care provided to patients. <u>Nothing in this provision shall prevent hospitals which are a part of a hospital system from having a unified and integrated medical staff as permitted by 42 C.F.R. § 482.22 (b) (4).</u></p> <p>B. The medical staff shall be responsible to the hospital governing board and maintain appropriate standards of professional performance through staff appointment criteria, delineation of staff privileges, continuing peer review and other appropriate mechanisms.</p> <p>C. The medical staff, subject to approval by the governing body, shall develop bylaws incorporating details of the medical staff organization and governance, giving effect to its general powers, duties, and responsibilities including:</p> <ol style="list-style-type: none"> 1. Methods of selection, election, or appointment of all officers and other executive committee members and officers; 2. Provisions for the selection and appointment of officers of departments or services specifying required qualifications; 3. The type, purpose, composition and organization of standing committees; 4. Frequency and requirements for attendance at staff and departmental meetings;

		<p>3. The type, purpose, composition and organization of standing committees;</p> <p>4. Frequency and requirements for attendance at staff and departmental meetings;</p> <p>5. An appeal mechanism for denial, revocation, or limitation of staff appointments, reappointments and privileges;</p> <p>6. Delineation of clinical privileges in accordance with the requirements of § 32.1-134.2 of the Code of Virginia;</p> <p>7. Requirements regarding medical records;</p> <p>8. A mechanism for utilization and medical care review; and</p> <p>9. Such other provisions as shall be required by hospital or governmental rules and regulations.</p> <p>D. A copy of approved medical staff bylaws and regulations and revisions thereto shall be made available to the OLC on request.</p>	<p>5. An appeal mechanism for denial, revocation, or limitation of staff appointments, reappointments and privileges;</p> <p>6. Delineation of clinical privileges in accordance with the requirements of § 32.1-134.2 of the Code of Virginia;</p> <p>7. Requirements regarding medical records;</p> <p>8. A mechanism for utilization and medical care review; and</p> <p>9. Such other provisions as shall be required by hospital or governmental rules and regulations.</p> <p>D. A copy of approved medical staff bylaws and regulations and revisions thereto shall be made available to the OLC on request.</p> <p>Intent: Clarify that the regulations are not intended to prevent unified and integrated medical staff in hospitals which are a part of a hospital system as permitted by federal regulation.</p> <p>Likely Impact: Greater clarity of the regulations.</p>
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1 Project 4521 - none

2

DEPARTMENT OF HEALTH

3

CH410-Amend to update for CMS rule change

4

5 **12VAC5-410-210. Medical staff.**

6 A. Each hospital shall have an organized medical staff responsible to the governing body of
7 the hospital for its own organized governance and all medical care provided to patients. Nothing
8 in this provision shall prevent hospitals which are a part of a hospital system from having a
9 unified and integrated medical staff as permitted by 42 C.F.R. § 482.22 (b) (4).

10 B. The medical staff shall be responsible to the hospital governing board and maintain
11 appropriate standards of professional performance through staff appointment criteria,
12 delineation of staff privileges, continuing peer review and other appropriate mechanisms.

13 C. The medical staff, subject to approval by the governing body, shall develop bylaws
14 incorporating details of the medical staff organization and governance, giving effect to its
15 general powers, duties, and responsibilities including:

- 16 1. Methods of selection, election, or appointment of all officers and other executive
17 committee members and officers;
- 18 2. Provisions for the selection and appointment of officers of departments or services
19 specifying required qualifications;
- 20 3. The type, purpose, composition and organization of standing committees;
- 21 4. Frequency and requirements for attendance at staff and departmental meetings;
- 22 5. An appeal mechanism for denial, revocation, or limitation of staff appointments,
23 reappointments and privileges;
- 24 6. Delineation of clinical privileges in accordance with the requirements of § 32.1-134.2
25 of the Code of Virginia;
- 26 7. Requirements regarding medical records;
- 27 8. A mechanism for utilization and medical care review; and
- 28 9. Such other provisions as shall be required by hospital or governmental rules and
29 regulations.

30 D. A copy of approved medical staff bylaws and regulations and revisions thereto shall be
31 made available to the OLC on request.



COMMONWEALTH of VIRGINIA

Department of Health

MARISSA J. LEVINE, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

PO BOX 2448
RICHMOND, VA 23218

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: November 5, 2015

TO: Virginia State Board of Health

FROM: Laurie Forlano, DO, MPH
Director, Office of Epidemiology

SUBJECT: Final Amendment to the *Regulations for Disease Reporting and Control* and Repeal of the *Regulations for Testing Children for Elevated Blood Lead Levels*

This regulatory action affects the requirements for testing children's blood to determine if they have been exposed to lead in the environment. The action involves the *Regulations for Disease Reporting and Control* and a related repeal of the *Regulations for Testing Children for Elevated Blood Lead Levels*.

The agency is incorporating the requirements for testing children to detect elevated blood lead levels into the *Regulations for Disease Reporting and Control* by adding a section numbered 12VAC5-90-215. In the same action, the existing regulations pertaining to testing children for lead, 12VAC5-120, is being repealed. Because the *Regulations for Disease Reporting and Control* include provisions for physicians and laboratories to report children with elevated blood lead levels to the health department, having a separate set of regulations that described which children should be tested was confusing to the regulated community. Combining both the testing and the reporting requirements into one set of regulations should make the process clearer to medical care providers.

The proposed amendment was printed in the Virginia Register on June 29, 2015; and the public comment period was extended through August 31, 2015. Two comments were received. One was supportive of the amendment, and the other requested consistency in the response to various blood lead test results. Public health action based on test results is determined by recommendations and guidelines rather than by regulation. Thus, no changes were made between the proposed and final amendment.

The Board of Health is asked to approve this final amendment at its December 2015 meeting. Following approval, the final amendment will be submitted to the Virginia Regulatory Town Hall to initiate Executive Branch review of the final regulation.



townhall.virginia.gov

Final Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-90 and 12VAC5-120
Regulation title(s)	Regulations for Disease Reporting and Control and Regulations for Testing Children for Elevated Blood Lead Levels
Action title	Updating Disease Reporting Regulations and Repealing Lead Testing Regulation
Date this document prepared	November 6, 2015

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*.

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.

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 public health reporting and disease control. The Virginia Department of Health is amending the regulations to bring them into compliance with recent changes in the field of environmental disease control that are needed to protect the health of the citizens of Virginia.

Specifically, the agency is incorporating the testing and risk determination criteria for identifying children with elevated blood lead levels into 12VAC5-90 and repealing 12VAC5-120, the existing regulation pertaining to blood lead testing of children.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

No acronyms are used without being defined in context.

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 State Board of Health approved the final amendment to the *Regulations for Disease Reporting and Control* on December 3, 2015.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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. §32.1-46.1 authorizes the Board to establish a protocol for the identification of children with elevated blood lead levels. 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. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.

The proposed amendment will improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for detectable blood lead levels in children. The changes will position the agency to better detect and respond to these environmental exposures 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.

The section on testing children to determine their blood lead levels is new to the *Regulations for Disease Reporting and Control* but reflects minor amendments to existing requirements that are currently included in another set of agency regulations, 12VAC5-120. The agency decided it was a logical and efficient change to incorporate the lead testing requirements into the set of regulations that addresses the reporting of elevated blood lead levels. Having one set of regulations on this topic should reduce confusion among the regulated community.

12VAC5-120, the existing regulation pertaining to the identification of children with elevated blood lead levels is being repealed as its content is being incorporated into 12VAC5-90. Some changes are also being made to simplify and clarify the requirements, remove unnecessary references to guidelines and non-mandatory actions, and reflect current Centers for Disease Control and Prevention recommendations. The proposed amendment to 12VAC5-90 pertaining to blood lead levels in children reflects a similar schedule of testing, risk factors for testing, criteria for determining low risk, and need for confirmatory testing as is currently provided in 12VAC5-120.

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 advantages to the public will be clearer rules for testing children for exposure to lead and less confusion that is inherent in maintaining two sets of regulations pertaining to the same subject and procedures.

The primary advantages to the agency are the same as for the public. That is, elimination of the confusion caused by needing to track multiple sets of regulations or the potential for inconsistent requirements in different regulations.

No disadvantages or other pertinent matters of interest to the regulated community have been identified.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is 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.

Family impact

Please assess the impact of this 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.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
		No changes	

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. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Public Health Nurse, Chesterfield Health District	Capillary lead levels 5-9 being repeated by preferred venous stick 1 – 3 mos. is new. No health department involvement until 10 – 44 with follow up 1 week – 1 month	No changes needed. Comment summarizes the new features of the requirement and is generally supportive of the change.

Commenter	Comment	Agency response
	<p>and case management. CDC will update the reference value every 4 years. I think this is clear and it's nice it is in one statute. Goes along with the fact sheet that we were given when the CDC lowered the level. I notice it is not "lead poisoning" or "level of concern" but "exposure to lead" below 10. Above 10 is "level requiring case management".</p>	
<p>United Parents Against Lead (UPAL)</p>	<p>Combining the two regulations into one will be less confusing, but the wording does nothing to ensure that children, even those deemed at-risk, will be tested for elevated blood lead levels. A major concern is that there is no uniform lead level of concern in Virginia. The action level varies from locality to locality (e.g., Henrico's is 20 ug/dL while Richmond/Chesterfield is 15 ug/dL). We should include wording in the regulations that would make the action level uniform across the state. Otherwise the testing and screening process that leads to case management and prompts residential lead inspections/risk assessments is convoluted and designed for failure to the detriment of our children. The Commonwealth's level should also be more in line with the CDC's reference value of 5 ug/dL. Moreover, once a child has tested high the home should be automatically inspected to determine if it is the source of poisoning. Testing "repeatedly and persistently" at elevated levels, does a disservice to our children and uses them as modern day canaries in the mines and reduces them to lead detectors.</p>	<p>None. This amendment pertains to identifying children in need of testing and establishing a schedule of testing for those in need. It does not address blood lead levels at which remedial actions should be taken or specific actions that are recommended in response to elevated levels. The reportable blood lead level is being addressed in a separate regulatory action, and specific actions taken at various levels are determined by public health procedures and clinical standards of practice rather than by regulation.</p>

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			None

2 DEPARTMENT OF HEALTH

3 Update Disease Reporting and Control Regulations
4 and Repeal Blood Lead Testing Regulations

5

6 Part IX.

7 Protocol for identification of children with elevated blood lead levels

8 12VAC5-90-215. Schedule and criteria for and confirmation of blood lead testing and
9 information to be provided.

10 A. Schedule for testing. Every child shall be tested to determine the blood lead level at 12
11 months and 24 months of age if the health care provider determines that the child meets any of
12 the criteria listed in subsection B of this section. Children 25 months through 72 months of age
13 who present for medical care and meet any of criteria of subsection B of this section shall also
14 be tested if they have either not previously been tested for blood lead level or were previously
15 tested but experienced a change since testing that has resulted in an increased risk of lead
16 exposure, based on the criteria listed in subsection B.

17 B. Criteria for testing.

18 1. The child is eligible for or receiving benefits from Medicaid or the Special
19 Supplemental Nutrition Program for Women, Infants and Children (WIC);

20 2. The child is living in or regularly visiting a house, apartment, dwelling, structure, or
21 child care facility built before 1960;

1 3. The child is living in or regularly visiting a house, apartment, dwelling, structure, or
2 child care facility built before 1978 that has (i) peeling or chipping paint or (ii) recent
3 (within the last six months) ongoing, or planned renovations;

4 4. The child is living in or regularly visiting a house, apartment, dwelling or other
5 structure in which one or more persons have blood lead testing yielding evidence of lead
6 exposure;

7 5. The child is living with an adult whose job, hobby, or other activity involves exposure
8 to lead;

9 6. The child is living near an active lead smelter, battery recycling plant, or other industry
10 likely to release lead;

11 7. The child's parent, guardian, or other person standing in loco parentis requests the
12 child's blood be tested due to any suspected exposure; or

13 8. The child is a recent refugee, immigrant, or is adopted from outside of the U.S.

14 C. Exceptions. A child who does not meet any of the above schedule or criteria is
15 considered to be at low risk, and testing is not required but may be conducted at the discretion
16 of the health care provider. The testing requirement shall be waived if the parent, guardian or
17 other person standing in loco parentis of a child objects to the testing on the basis that the
18 procedure conflicts with his religious tenets or practices.

19 D. Confirmation of blood lead levels. Blood lead level testing shall be performed on venous
20 or capillary blood. Tests of venous blood performed by a laboratory certified by the federal
21 Health Care Financing Administration in accordance with Clinical Laboratory Improvement
22 Amendment of 1988 (CLIA-certified) are considered confirmatory. Tests of venous blood
23 performed by any other laboratory and tests of capillary blood shall be confirmed by a repeat

1 blood test, preferably venous, performed by a CLIA-certified laboratory. Such confirmatory
2 testing shall be performed in accordance with the following schedule:

3 1. Within one to three months if the result of the capillary test is at or above the CDC's
4 reference value and up to 9 micrograms of lead per deciliter of whole blood ($\mu\text{g}/\text{dL}$).

5 2. Within one week to one month if the result of the capillary test is 10-44 $\mu\text{g}/\text{dL}$. The
6 higher this test result, the more urgent the need for a confirmatory test.

7 3. Within 48 hours if the result of the capillary test is 45-59 $\mu\text{g}/\text{dL}$.

8 4. Within 24 hours if the result of the capillary test is 60-69 $\mu\text{g}/\text{dL}$.

9 5. Immediately as an emergency laboratory test if the result of the capillary test is 70
10 $\mu\text{g}/\text{dL}$ or higher.

11 E. Information to be provided. As part of regular well-check visits for all children, the health
12 care provider shall make available to parents, guardians, or other persons standing in loco
13 parentis information on the dangers of lead poisoning, potential sources of lead and ways to
14 prevent exposure, and a list of available lead-related resources. When blood lead level testing
15 is performed, the health care provider shall share the child's blood lead level test result with the
16 child's parent, guardian, or other person standing in loco parentis and report to the health
17 department in accordance with the requirements of 12VAC5-90-80.

1 CHAPTER 120

2 REGULATIONS FOR TESTING CHILDREN FOR ELEVATED BLOOD-LEAD LEVELS

3 Part I

4 Definitions and General Information

5 **12VAC5-120-10. Definitions. (Repealed.)**

6 ~~The following words and terms when used in this chapter shall have the following meanings~~
7 ~~unless the context clearly indicates otherwise:~~

8 ~~"Board" means the State Board of Health.~~

9 ~~"Commissioner" means the Commissioner of Health.~~

10 ~~"Elevated blood-lead level" for children means 10 or more micrograms of lead per deciliter of~~
11 ~~whole blood in a child up to and including 72 months of age.~~

12 ~~"Health care provider" means a physician or his designee or an official of a local health~~
13 ~~department.~~

14 ~~"High-risk ZIP Code area" means a ZIP Code area listed in guidelines issued by the Virginia~~
15 ~~Department of Health in which 27% or more of the housing was built before 1950 or 12% or~~
16 ~~more of the children have elevated blood-lead levels based on current available data.~~

17 ~~"Physician" means a person licensed to practice medicine in any of the 50 states or the~~
18 ~~District of Columbia.~~

19 ~~"Point of care testing" refers to testing by a health care provider that has a CLIA Certificate~~
20 ~~of Waiver.~~

21 ~~"Qualified laboratory" means a laboratory that is certified by the Health Care Financing~~
22 ~~Administration in accordance with the Clinical Laboratory Improvement Amendments of 1988~~

1 ~~(CLIA) (42 CFR Part 493) and is participating in the Centers for Disease Control and~~
2 ~~Prevention's (CDC) Blood Lead Laboratory Proficiency Program.~~

3 "µg/dL" means micrograms of lead per deciliter of whole blood.

4 **12VAC5-120-20. Statement of general policy. (Repealed.)**

5 ~~The Commonwealth of Virginia has recognized the need for early identification of children~~
6 ~~with elevated blood lead levels to alert parents and guardians to the need for intervention to~~
7 ~~prevent physical, developmental, behavioral, and learning problems associated with elevated~~
8 ~~blood lead levels in children, and to prevent exposure of other children.~~

9 ~~The purpose of this chapter is to provide a protocol for identifying children with elevated~~
10 ~~blood lead levels.~~

11 ~~The department encourages health care providers, parents and guardians to exercise~~
12 ~~reasonable, but liberal judgment and discretion in implementing and applying the protocol set~~
13 ~~forth in this chapter, so that the health of all Virginia's children may be protected from lead~~
14 ~~poisoning.~~

15 Part II

16 Protocol for Identification of Children with Elevated Blood-Lead Levels

17 **12VAC5-120-30. Schedule for testing. (Repealed.)**

18 ~~Virginia health care providers should test all children up to and including 72 months of age~~
19 ~~for elevated blood lead levels according to the following schedule unless they are determined~~
20 ~~under 12VAC5-120-60 to be at low risk for elevated blood lead levels. All blood lead samples~~
21 ~~shall be analyzed by a qualified laboratory. The use of a CDC approved and CLIA-waived~~
22 ~~instrument for point-of-care testing, as a means of administering screening tests for elevated~~
23 ~~blood lead levels, is exempted from the requirement to have all blood lead samples analyzed by~~
24 ~~a qualified laboratory. However, any elevated blood lead level found through point-of-care~~

1 ~~testing to be equal to or greater than 10 µg/dL shall be confirmed by a venous blood lead test~~
2 ~~performed by a qualified laboratory in accordance with the requirements of 12VAC5-120-40.~~

3 ~~1. Children should be tested at ages one and two years.~~

4 ~~2. Children from 36 through 72 months of age should be tested if they have never been~~
5 ~~tested.~~

6 ~~3. Additional testing may be ordered by the health care provider.~~

7 ~~4. Children should be tested at the request of a parent or guardian due to any suspected~~
8 ~~exposure.~~

9 **~~12VAC5-120-35. Information about lead poisoning. (Repealed.)~~**

10 ~~The health care provider shall make available to parents information on the dangers of lead~~
11 ~~poisoning, along with a list of available resources, as part of regular well-check visits for all~~
12 ~~children up to 72 months of age.~~

13 **~~12VAC5-120-40. Confirmation of blood-lead levels. (Repealed.)~~**

14 ~~Testing may be performed on venous or capillary blood collected in tubes or on filter paper.~~
15 ~~If a test of capillary blood reveals an elevated blood-lead level, the results shall be confirmed by~~
16 ~~a repeat blood test (preferably venous):~~

17 ~~1. Within three months if the result of the capillary test is 10 µg/dL to 19 µg/dL.~~

18 ~~2. Within one week to one month if the result of the capillary test is 20 µg/dL to 44 µg/dL.~~

19 ~~The higher this test result, the more urgent the need for a confirmation test.~~

20 ~~3. Within 48 hours if the result of the capillary test is 45 µg/dL to 59 µg/dL.~~

21 ~~4. Within 24 hours if the result of the capillary test is 60 µg/dL to 69 µg/dL.~~

22 ~~5. Immediately as an emergency laboratory test if the result of the capillary test is 70~~
23 ~~µg/dL or higher.~~

1 ~~Elevated blood lead results from venous blood testing shall be deemed a confirmed test.~~

2 **12VAC5-120-50. Risk factors requiring testing. (Repealed.)**

3 ~~A health care provider shall test any child for elevated blood lead level, or have such a child~~
4 ~~tested, if the provider determines, in the exercise of medical discretion, that such testing is~~
5 ~~warranted, and that the child meets one or more of the following criteria:~~

6 ~~1. Eligible for or receiving benefits from Medicaid or the Special Supplemental Nutrition~~
7 ~~Program for Women, Infants and Children (WIC);~~

8 ~~2. Living in a high-risk zip code area;~~

9 ~~3. Living in or regularly visiting a house or child care facility built before 1950;~~

10 ~~4. Living in or regularly visiting a house, apartment, dwelling or other structure, or a child~~
11 ~~care facility built before 1978, with peeling or chipping paint or with recent (within the last~~
12 ~~six months), ongoing, or planned renovations;~~

13 ~~5. Living in or regularly visiting a house, apartment, dwelling or other structure in which~~
14 ~~one or more persons have elevated blood lead levels;~~

15 ~~6. Living with an adult whose job or hobby involves exposure to lead as described in~~
16 ~~Preventing Lead Poisoning in Young Children (CDC, 1991);~~

17 ~~7. Living near an active lead smelter, battery recycling plant, or other industry likely to~~
18 ~~release lead;~~

19 ~~8. The child's parent or guardian requests the child's blood be tested due to any~~
20 ~~suspected exposure; or~~

21 ~~9. A health care provider recommends the child's blood be tested due to any suspected~~
22 ~~exposure.~~

23 ~~The Department of Health will maintain a list of high-risk zip code areas in Virginia.~~

1 **~~12VAC5-120-60. Determination of low risk for elevated blood-lead levels. (Repealed.)~~**

2 ~~Blood-lead testing is not indicated for children determined by a health care provider to be at~~
3 ~~low risk for elevated blood-lead levels. A health care provider may determine a child to be at low~~
4 ~~risk for elevated blood-lead level if the child meets none of the criteria listed in 12VAC5-120-50,~~
5 ~~but is encouraged to cause a child to be tested if, in the exercise of discretion and consideration~~
6 ~~of the various means by which exposure to lead may occur, such exposure cannot be clearly~~
7 ~~ruled out.~~

8 **~~12VAC5-120-70. Samples submitted to a qualified laboratory. (Repealed.)~~**

9 ~~A. All blood samples submitted to a qualified laboratory for analysis shall be accompanied~~
10 ~~by a completed laboratory requisition with all of the required data as determined by the~~
11 ~~Department of Health.~~

12 ~~B. All qualified laboratories accepting blood samples for lead analysis under this chapter~~
13 ~~shall submit all required data to the board within 10 business days of analysis. The data shall be~~
14 ~~sent by a secure electronic means that has been approved by the Department of Health.~~

15 ~~C. Any laboratory reporting under this section shall be deemed in compliance with the~~
16 ~~stipulations of § 32.1-36 of the Code of Virginia and 12VAC5-90-90 of the Board of Health~~
17 ~~Regulations for Disease Reporting and Control.~~

18 **~~12VAC5-120-80. Follow-up testing and information. (Repealed.)~~**

19 ~~The Department of Health will establish guidelines for follow-up testing for children with~~
20 ~~confirmed elevated blood-lead levels, provide or recommend appropriate information for~~
21 ~~parents, and disseminate through various available means the protocol and other information to~~
22 ~~all relevant health care professionals. The department encourages health care professionals to~~
23 ~~conduct whatever follow-up testing is indicated or warranted in the exercise of medical or clinical~~
24 ~~judgment and discretion.~~

1 ~~12VAC5-120-90. Exclusion from testing when risk is low and on religious grounds.~~

2 ~~**(Repealed.)**~~

3 ~~In accordance with § 32.1-46.2 of the Code of Virginia, every child in the Commonwealth~~
4 ~~should be tested for elevated blood-lead levels or determined to be at low risk for elevated~~
5 ~~blood-lead levels unless the parent, guardian or other person standing in loco parentis obtains a~~
6 ~~determination that the child is at low risk for elevated blood-lead levels or unless the parent,~~
7 ~~guardian or other person having control or charge of such child objects to such testing on the~~
8 ~~basis that the procedure conflicts with his religious tenets or practices.~~



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: November 16, 2015

TO: Virginia State Board of Health

FROM: Laurie Forlano, DO, MPH
State Epidemiologist & Director, Office of Epidemiology

SUBJECT: Final Amendment to the *Regulations for Disease Reporting and Control*

This set of amendments to the *Regulations for Disease Reporting and Control* represents a general update to language throughout the regulations to align reporting requirements with current public health practice and current laboratory technology. The proposed amendments included many minor modifications that remain unchanged in the final amendment. Examples include specifying that reporting ‘by the most rapid means available’ means ‘immediately’ in each section where rapid reporting is mentioned and changing numbering of subsections to ensure internal consistency. In the proposed and final amendments, babesiosis and leptospirosis were added to the reportable disease list in accordance with national recommendations and monkeypox and methicillin-resistant *Staphylococcus aureus* (MRSA) infection were deleted because other means of capturing these data are available.

Comments were received from 23 persons, including 7 from outside the Virginia Department of Health (VDH). Based on the comments, changes that have been incorporated into the final amendment include edits to definitions, reportable disease lists, information for those required to report, and childhood immunizations. Details of changes in each of these sections are provided below.

12VAC5-90-10. Definitions.

- A definition was added for ‘Coronavirus infection, severe’ that includes severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) in response to confusion expressed about the proposal to add MERS to the previous SARS definition. With this addition, the definition for SARS is being deleted.

- Because commenters also found the reference to a CDC document for reportable blood lead levels to be confusing, the final amendment states that any detectable level in children and blood lead levels ≥ 5 ug/dL in those over 15 years of age are reportable. This reportable condition will now be referred to as ‘Lead, Reportable Levels’ rather than ‘Lead, Elevated Blood Levels’.
- The definitions for hepatitis C have been updated to be consistent with current national reporting definitions, and the definition of ‘department’ was expanded to refer to VDH.

12VAC5-90-80. Reportable Disease Lists

- ‘Coronavirus infection, severe’ is being added to the list of reportable conditions and SARS is being deleted to align the list with the definitions and to capture not only SARS but also MERS or any other coronavirus that may cause a severe illness.
- Many new laboratory tests have been added in the list of conditions reportable by laboratory directors. Laboratory technology is evolving rapidly and new tests, especially those that involve molecular identification, need to be added so public health will receive the information necessary to conduct surveillance.
- Additional changes for laboratory directors that were in the proposed amendment that persist in the final version include requiring them to provide additional information on hepatitis test results and antimicrobial susceptibility for gonorrhea. Amendments also require lab directors to submit remnant sera from HIV positive diagnostic tests to DCLS or another approved lab for HIV recency testing and provide electronic HIV genetic sequence data from HIV drug resistance tests. Labs will also be required to submit all (positive and negative) HIV test results for children under 3 years of age.
- The requirement for labs to report all hepatitis B test results for children under 2 years of age was deleted in the final amendment. VDH only needs positive results, and those are already reportable.

12VAC5-90-90. Those Required to Report

- Language has been added to clarify that HIV genetic nucleotide sequence data associated with HIV drug resistance tests must be submitted electronically.
- Clarification of the requirement for laboratories to send HIV sera left after diagnostic testing was also added to indicate that this applies to available sera from positive tests.
- Botulism and tularemia were added to the list of conditions for which labs are required to submit specimens to the state laboratory for further testing.

- Language was added to allow reporting on a VDH form in addition to a CDC form, to identify telephone as the preferred method of immediate reporting, and to require physician reports to include available information on lab tests and results.

12VAC5-90-110. Immunization of Persons Less Than 18 Years of Age

- This section was updated to state that licensed professionals can provide the required immunizations as authorized by the Code of Virginia. In the final amendment, reference to ‘private settings or local health departments’ was stricken as it was unnecessary.

12VAC5-90-280. Reporting of Dangerous Microbes and Pathogens

- No changes have been made to this section since the proposed amendment. Changes will include updating the section to comply with federal regulations and to specify that the information is protected regardless of what entity provides the information to the department.

These changes will improve the department’s ability to detect and control conditions of public health concern that are affecting the residents of Virginia. Following approval of the final amendments by the Board, the department intends to submit the regulatory packet to the Virginia Town Hall for Executive Branch review.



townhall.virginia.gov

Final Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-90
Regulation title(s)	Regulations for Disease Reporting and Control
Action title	Amendment to comply with changes in public health practice
Date this document prepared	November 12, 2015

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*.

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.

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 public health reporting and disease control. The Virginia Department of Health is proposing an amendment to the regulations in order to bring them into compliance with recent changes in the field of communicable disease control and emergency preparedness that are needed to protect the health of the residents of Virginia.

The specific changes being proposed are necessary to ensure the regulations comply with recent changes in the practice of public health pertaining to the reporting of diseases in humans that are potentially transmitted from environmental sources (e.g., babesiosis and leptospirosis) as well as to update the list of laboratory tests that can be used to identify reportable disease findings and of specimens needing further testing to reflect advances in laboratory technology. Further amendments are

necessary to clarify definitions and ensure consistency of the regulatory language, such as to standardize the reporting requirements for those who are required to report. Minor changes are also proposed to the section on the reporting of dangerous microbes to align the regulatory requirements with federal requirements. Renumbering is proposed for internal consistency and to ensure relevant sections are maintained as a whole.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

CDC – Centers for Disease Control and Prevention
 DCLS – Division of Consolidated Laboratory Services
 FBI – Federal Bureau of Investigation
 HIV – Human Immunodeficiency Virus
 MERS – Middle East Respiratory Syndrome
 SARS – Severe Acute Respiratory Syndrome
 VDH – Virginia Department of Health

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 State Board of Health approved the final amendment to the *Regulations for Disease Reporting and Control* on December 3, 2015.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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*.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.

The amendment is necessary in order to ensure that the regulations comply with changes in the *Code of Virginia* and recommendations of national public health organizations. 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 outbreaks and emergencies that could be caused by naturally occurring disease or acts of bioterrorism. 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.

- Update definitions to align them with current usage;
- Update the reportable disease list to reflect current national recommendations and language;
- Update the list of conditions reportable by laboratory directors to reflect current laboratory technology and public health standards;
- Increase the information reported by laboratory directors for hepatitis B and human immunodeficiency virus testing and the specimens to be submitted to the Division of Consolidated Laboratory Services or other lab designated by the agency for advanced laboratory testing;
- Update language to ensure consistency between sections;
- Clarify agency role in interstate and national notifications;
- Clarify level of information that may be shared with the agency by schools and other facilities;
- Renumber sections to increase internal consistency within the regulations;
- Update reporting of dangerous microbes and pathogens sections to reflect federal code section numbering changes and other requirements.

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 the public is that the Virginia Department of Health will be increasingly aware of conditions of public health concern so that staff can take action to reduce the risk of preventable acute diseases. No disadvantages to the public are known.

The primary advantage to the agency is that the proposed amendments will improve the ability of the Virginia Department of Health to detect and control diseases of public health importance. Most of the changes being proposed are updates to terminology to reflect current usage or to clarify requirements. Some formatting changes have also been proposed.

The impact on businesses primarily affects laboratories conducting business in the Commonwealth. The addition of laboratory testing methods to the list of conditions that laboratory directors must report reflects advances in laboratory science, but would mean that laboratories conducting business in Virginia will have to report additional positive laboratory findings to the health department. Many of the proposed changes are already being reported by laboratories who offer those testing options.

The amendments would require laboratory directors to provide additional information on hepatitis test results and antimicrobial susceptibility for gonorrhea. Amendments also require lab directors to submit remnant sera from HIV positive diagnostic tests to DCLS or another approved laboratory for HIV recency testing and provide electronic genetic sequence data from HIV drug resistance tests. They would also report all HIV test results for children under 3 years of age. Another noteworthy change is that the reportable blood lead level is proposed to be any detectable level for children and $\geq 5 \mu\text{g/dL}$ for persons 15 years of age or older.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is 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.

Family impact

Please assess the impact of this 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.

Changes made since the proposed stage

Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-90-10	<p>Arboviral infection definition referred to chikungunya but did not define an acronym; 'Acute care hospital', 'adult intensive care unit', 'central-line associated bloodstream infection', and 'central line device' were defined but not used in the subsequent text; Definitions for 'companion animal', 'essential needs', and 'school' were not consistent with Code; 'Coronavirus infection, severe' was captured under SARS; Definition of 'department' referred to the 'State Department of Health'; Throughout 'health care' was proposed as a change from 'healthcare'; Definition for hepatitis C referred to signal-to-cutoff ratio and RIBA test and 400 as the criteria for liver enzyme levels; Definition of elevated blood lead levels was set at CDC reference levels and the latest (2012) reference levels were provided.</p>	<p>Acronym 'CHIK' was added for the arbovirus, chikungunya; Definitions for the four terms that were not used later were deleted; Definitions were edited to ensure consistency with the <i>Code of Virginia</i>; Separate definition was added for 'Coronavirus infection, severe' and the definition for SARS was deleted; Definition of 'department' was expanded to include the 'Virginia Department of Health' and to introduce the acronym 'VDH'; Changed back to the original use of 'healthcare'; Definition for hepatitis C was updated to delete reference to signal-to-cutoff ratio and RIBA test and to lower the criteria for liver enzyme levels to 200; Definition of reportable blood lead levels was updated to refer to any detectable level in children (15 years of age and younger) and ≥ 5 $\mu\text{g}/\text{dL}$ in those over the age of 15 years.</p>	<p>Defined the acronym for chikungunya so it could be used in 12VAC5-90-80; It was unnecessary to define terms that were not used; Discrepancies between Code and Regulations on these terms were eliminated; Combining the definitions for SARS and MERS under the definition of SARS was confusing, putting them both under coronavirus helps make the definition clearer; Defining VDH allows the acronym to be used later in the document; 'Healthcare' is the phrase used most often; Laboratory techniques and surveillance definitions for hepatitis C have changed and the new language reflects current usage; Defining specific reportable levels will be clearer for laboratories rather than incorporating a reference that is expected to change over time.</p>
12VAC5-90-80	<p>The requirement to report arboviral diseases did not specify that it included CHIK; SARS was a reportable disease and the intent to use that heading to also capture MERS and other serious coronavirus</p>	<p>Added reference to 'CHIK' under arboviral diseases; Added 'coronavirus infection, severe' to reportable disease list and deleted SARS in Sections A, B, and C; For campylobacteriosis added required reporting of culture results from nucleic acid detection</p>	<p>Chikungunya is an important emerging arboviral disease and the Agency wanted to ensure those who report diseases knew it was reportable; Combining SARS and MERS under a new</p>

Section number	Requirement at proposed stage	What has changed	Rationale for change
	<p>infections was included in 12VAC5-90-10; For campylobacteriosis, the Agency proposed to require laboratories to report culture results from antigen detection tests; ‘Lead, elevated blood levels’ was the term used for this reportable condition; The Agency proposed to require reporting of outbreaks of ‘health care-associated infections’; Laboratory methodologies listed for the following diseases were not inclusive of current technology: anthrax, babesiosis, cholera, ehrlichiosis/anaplasmosis, E. coli, Shiga toxin-producing, gonorrhea, hepatitis B, hepatitis C, HIV, lead, listeriosis, meningococcal disease, pertussis, Q fever, salmonellosis, shigellosis, streptococcal disease, syphilis, typhoid/ paratyphoid fever, and Vibrio infection.</p>	<p>tests; ‘Lead, reportable levels’ is the new term being used in this regulation for this reportable condition; The Agency requires reporting of outbreaks of ‘healthcare-associated infections’; Updated the reportable laboratory methodologies for all the diseases listed in the column to the left.</p>	<p>category referred to as coronavirus will clarify the reporting requirement; For campylobacteriosis, the accuracy of antigen detection and nucleic acid detection tests is unknown and more information is needed about culture confirmation for both tests; ‘Healthcare’ is the proper term to use in this instance; The definition of reportable blood lead levels required the change in nomenclature; Laboratory methodologies for infectious diseases are rapidly evolving and public health inserted edits to reflect the latest laboratory tests in use to confirm the diagnosis of reportable conditions.</p>
<p>12VAC5-90-90</p>	<p>No mention was made of directors of laboratories needing to report genetic nucleotide sequence data associated with HIV drug resistance tests electronically or to forward remnant sera from HIV positive diagnostic tests to DCLS, the state laboratory, or other approved laboratory; Reporting on Epi-1 forms or CDC surveillance forms was allowed; Mentioned reporting by the most rapid means available; Botulism and tularemia were not included in the</p>	<p>The requirements related to HIV surveillance were added; Permission to also report using a VDH surveillance form was added; Specific language was inserted throughout to identify telephone reporting as the preferred method for immediate reporting; Botulism and tularemia were added to the list of specimens labs have to send to the state lab; Added available lab tests and results to information to be reported by physicians; Edited content to refer to ‘laboratory directors’ in place of extraneous words that were already included in the definition, to clarify that physicians request the lab tests, to correct a</p>	<p>Genetic sequence data are reported in large files that do not lend themselves to keying into a database; Further testing of positive HIV sera at a designated recency lab will aid in HIV surveillance locally and nationwide as it provides a more accurate picture of the spread of new HIV infections and helps to more clearly identify groups who are contracting HIV and where prevention efforts should be focused; Specialized testing available at the state lab</p>

Section number	Requirement at proposed stage	What has changed	Rationale for change
	list of specimens that lab directors have to submit to the state lab; Lab data were not included in the required contents of physician reports; Some unclear, inaccurate, or excessive terminology was included.	typographical error in the sentence about reporting to CDC, and to make a change in one place that had been missed before (to change 'applicants' to 'conditional employees' in section G).	is necessary to confirm these organisms; Public health will be able to take action more quickly if confirmatory laboratory data are included in initial disease reports; Edits clarify and correct language included in the proposed text.
12VAC5-90-110	Language was included that stated that immunizations could be given by licensed professionals in private settings or local health departments.	The reference to setting locations was deleted.	The language was not necessary.

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. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Infection Preventionist, Central Region	Town Hall – Add Middle East Respiratory Syndrome (MERS) to Severe Acute Respiratory Syndrome (SARS) for clarification.	Under Definitions and sections A, B, and C of 12VAC5-90-80, deleted SARS and added 'coronavirus infection, severe', noting that it pertains to SARS and MERS
District Health Director, Central Region	Town Hall – 1) Recommend not lowering the reportable blood lead level unless that level causes harm and actions can reduce the lead in the blood; 2) Recommend requiring laboratories to report to the health department of the patient's residence or the ordering physician or facility rather than where the lab is located or establish one number in the central office where disease reports can come in and be dispatched to the proper locality.	Regarding item 1), lowering the reportable blood lead level will aid in identifying children exposed to lead and help eliminate the problem of lead in the environment. No safe blood lead level exists. Regarding item 2), allowing facilities to send all disease reports to the local health department where they are located minimizes the reporting burden and aids in compliance. No changes are necessary. The Agency will consider the feasibility of establishing a disease report call line in the future.
VDH Epidemiologist, Central Office Foodborne Program	Email – Could labs be asked to report tests that are positive 'by any method' rather than specifying the methods?	The Agency will consider the feasibility and possible impact of making this change in the future.
VDH District Epidemiologist,	Email – Requested interpretation of proposed requirement for labs to	Only positive results for hepatitis B in children are needed. As they are already required, this

Commenter	Comment	Agency response
Southwest Region	report all hepatitis B findings in children under 2 years of age and all HIV results in children under 4 years of age.	proposed change was deleted. The requirement for all HIV results in children <3 was reworded to be clearer in the final text.
VDH Epidemiologist, HIV Program	Email - Recommended changes in the laboratory reporting requirements for HIV infection clarifying that undetectable viral loads are included and added language in 12VAC5-90-80.B and 12VAC5-90-90 to state that genetic sequence data on HIV drug resistance must be submitted electronically.	These changes have been incorporated into the final text.
Infection Preventionist, SW Region	Email – Supportive of proposed changes.	No change necessary
Private Lab Director, SW Region	Email – 1) Requested clarification on the age for children for whom all HIV test results would be reported; 2) reported that labs cannot report liver function test results; and 3) asked if IgG above the reference range with a negative IgM for West Nile virus should be reported.	Regarding item 1), the Agency HIV surveillance program clarified that age <3 is intended and that is reflected in the final text. Regarding item 2), the regulations state that those results should be submitted by labs if available. Regarding item 3), labs must report serologic evidence of recent infection, so while reports of both IgM and IgG are helpful from a clinical perspective, IgG results are not required to be reported to VDH. Labs may continue to voluntarily submit IgG results along with any IgM results for WNV.
Plasma Services Center, Central Region	Letter – Stated that it would create a staff and financial burden to submit HIV positive samples to the state lab (DCLS) and they would need technical information before they could ship.	Plasma centers and blood donation centers performing only donor screening tests are not subject to submitting HIV diagnostic remnant sera to DCLS or a lab designated by VDH for recency testing. That requirement pertains only to confirmatory diagnostic tests and not to screening tests.
Major Health System, Central Region	Letter – 1) To report all the hepatitis and HIV results in children would require 6 months of work by the IT team; 2) submitting HIV remnant sera to DCLS would have significant staffing implications, with labor and shipping costs; 3) shipment of influenza specimens is equally burdensome; 4) clarify request for coronavirus is for more serious strains such as MERS or SARS; 5) add smear evaluation to the test methodologies for Babesia; 6) clarify responsibility for reporting results generated by outside reference labs (they come as large text records).	Regarding item 1), the Agency understands implementation challenges and will be supportive of reporting as institutions transition to new methods of reporting. The requirement for reporting all hepatitis results in young children was deleted in the final text. Regarding item 2), the importance of improving the understanding of HIV infection and detecting recency of infection are significant. HIV Incidence Surveillance (HIS) is conducted in only 25 jurisdictions, including Virginia; HIS estimates provide a more accurate picture of the spread of new HIV infections and help to more clearly identify groups who are contracting HIV and where prevention efforts should be focused. Securing remnant diagnostic sera from laboratories confirming positive HIV tests is crucial for the estimation

Commenter	Comment	Agency response
		<p>process. Laboratories currently submit sera voluntarily and Virginia has struggled to attain the required benchmark that is needed so as to get estimates that are stable and reliable. Other jurisdictions have found that having regulations that require remnant sera to be submitted for recency testing improves the success of the program. The Agency will discuss logistical options with facilities. Regarding item 3), only novel influenza viruses have to be forwarded to DCLS, and those should not occur unless a pandemic may be beginning, in which case further identification of the virus is necessary. Regarding item 4), this issue has been addressed in the final text as stated above. Regarding item 5), this addition was made in the final text. Regarding item 6), laboratories in Virginia need to report the results of tests they run in house or those run by an out-of-state reference lab. They do not have to report results generated by in-state reference labs, which fall under the reporting requirements of the Board of Health.</p>
<p>VDH Epidemiologist, Central Office Surveillance Program</p>	<p>Email - What blood lead levels should laboratories report?</p>	<p>The final amendment reflects the requirement for laboratories to report all detectable blood lead levels in children age 0-15 years and ≥ 5 $\mu\text{g}/\text{dL}$ in those >15 years of age</p>
<p>VDH State Epidemiologist</p>	<p>Email – 1) expressed concern about noting the current (2012) blood lead levels and suggested creating an annual companion document for labs with reference levels in case the levels change; 2) requested consensus on the MERS/SARS language; 3) suggested changes in 12VAC5-90-110 related to wording about licensed professionals who can administer immunizations and where.</p>	<p>Regarding item 1), the confusion about reportable blood lead levels has been resolved in a way that referring to a separate document will not be necessary. Regarding item 2), this issue has been addressed in the final text. Regarding item 3), this change was incorporated into the final text.</p>
<p>District Health Director, Northern Region</p>	<p>Email - Suggested changing the rapid reporting language from 'immediately by the most rapid means available' to 'immediately by telephone to the local health department emergency contact'</p>	<p>The requirement to report by the most rapid means available specifies that telephone reporting is preferable. The preference for telephone reporting was added each time mention was made of immediate reporting.</p>
<p>VDH Division Director, Central Office, Disease Prevention</p>	<p>Email - Suggested changes to the lab reporting requirements for syphilis and gonorrhea</p>	<p>These changes have been incorporated into the final text</p>
<p>Infectious disease physician, NW</p>	<p>Email – Sought clarification as to whether VDH wants all HIV viral loads, CD4 counts, and resistance</p>	<p>That is the Agency's intent in order to allow monitoring of treatment effectiveness. No change is necessary.</p>

Commenter	Comment	Agency response
Region	test results on all patients for the rest of their lives.	
VDH Perinatal Hepatitis B Coordinator	Email – Stated that the program does not need negative lab results on children under 2 years of age for hepatitis B	This requirement was deleted from the final text.
VDH Division Director, Environmental Epidemiology	Email - Recommended a change to wording in the reportable level for elevated blood lead levels, removing the reference to the current CDC level and instead suggesting that reference documents be incorporated by reference into the regulation.	The requirement was changed to all detectable blood lead levels being reportable in children and levels ≥ 5 in persons over 15 years of age, thereby simplifying and clarifying the requirement and eliminating the need for guidance documents for laboratories.
Director, Division of Consolidated Laboratory Services	Email – 1) Suggested many updates related to laboratory test methods in 12VAC5-90-80.B, conditions reportable by laboratory directors. 2) Recommended deleting reference to the RIBA test for hepatitis C in the Definitions section and the Lab reporting section. 3) Recommended against combining MERS with SARS.	Regarding item 1), all proposed changes were reviewed carefully and compared with national case definitions. Changes were made throughout the list to ensure it reflected current and anticipated laboratory methods. Regarding item 2), reference to the RIBA test was deleted in both places. Regarding item 3), the coronavirus item has been addressed.
VDH Epidemiologist, Central Office, Foodborne Program	Email – 1) Stated that retaining the different genres under vibriosis was important and suggested that we refer to the Family Vibrionaceae (other than toxigenic V cholera O1 or O139); 2) suggested requiring the reporting of culture-independent diagnostic tests for enteric pathogens and coordinating with DCLS to determine which specimens should be forwarded to the state lab if they test positive by a non-culture lab method.	Regarding item 1), the suggested wording has been incorporated into final text. Regarding item 2), the use of antigen detection and nucleic acid detection tests have been added to lab reporting requirements for enteric pathogens. The discussion of a requirement for laboratories to forward specimens to DCLS for additional conditions must be deferred until a future regulatory amendment so that laboratory directors will have an opportunity to comment on proposed changes.
VDH Epidemiologist, Central Office, Reportable Disease Surveillance	Email – Reviewed the laboratory reporting requirements compared to national case definitions and recommended changes throughout to ensure consistency between the documents.	All proposed changes were reviewed carefully and compared with national case definitions and the recommendations of DCLS. Changes were made throughout the list to ensure it reflected current and anticipated laboratory methods.
VDH Epidemiologist, Central Office Manager	Email – Recommended that VDH consider whether the definition of laboratory needs to be changed to clearly include blood collection centers and plasma centers.	The Agency verified that the definition of laboratory did not need to be amended.
VDH Epidemiologist, Central Office, Immunizations	Email – Encouraged the addition of serologic tests to reportable laboratory tests for pertussis; recommended changes to 12VAC5-90-110 clarifying professionals that can give immunizations.	Both of these recommendations are reflected in the final text.

Commenter	Comment	Agency response
VDH District Health Director, Central Region	Email - Asked for clarification as to whether school nurses can give immunizations under 12VAC5-90-110.	Agency verified that the <i>Code of Virginia</i> specifies that school nurses are not allowed to administer vaccines to minors unless a prescriber is on-site. No change in the regulatory language is necessary.
VDH Director of Public Health Nursing	Email - Asked who will provide updated guidelines for follow up testing and evaluation of children with elevated blood lead levels.	The VDH Division of Environmental Epidemiology and VDH Office of Environmental Health Lead Safe Program can assist with this effort.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Multiple		Multiple	All changes listed in the table above under the heading 'Changes made since the proposed stage'.
12VAC5-90-10		Definitions	<ul style="list-style-type: none"> • Defines Centers for Disease Control and Prevention (CDC) and changes its usage upon later referral. • Changes capitalization on 'Ehrlichiosis/Anaplasmosis' for consistency.
12VAC5-90-50	Repeal	Applicability Section	<ul style="list-style-type: none"> • This section stated that the regulations apply throughout the Commonwealth and are governed by the Administrative Process Act. Legislative Services advised that it is not necessary and is redundant with Code requirements.
12VAC5-90-80.A		Reportable disease list	<ul style="list-style-type: none"> • Additions to the reportable disease list include babesiosis and leptospirosis. • Deletes monkeypox from the reportable disease list. The Department has other means of receiving data on the occurrence of this disease.
12VAC5-90-80.B		Conditions reportable by directors of laboratories	<ul style="list-style-type: none"> • Additions include babesiosis, hepatitis-other acute viral, and leptospirosis. • Deletions include monkeypox and methicillin-resistant <i>Staphylococcus aureus</i> infections. • Changes are proposed to the reportable results for botulism, Campylobacter infection, <i>E. coli</i> infection, giardiasis, gonorrhea, hepatitis B, hepatitis C, HIV,

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			lead, salmonellosis, shigellosis, Staphylococcal infection, and Vibrio infection to incorporate current laboratory methods. <ul style="list-style-type: none"> • Laboratories would report all HIV results for children under 3 years of age. • Laboratories would submit all remnant HIV sera to the Division of Consolidated Laboratory Services (DCLS) or other designated laboratory for HIV recency testing and would report all HIV genetic sequence data associated with HIV drug resistance testing.
12VAC5-90-80.C-F		Rapidly reportable conditions, toxic substances, outbreaks, and unusual diseases	<ul style="list-style-type: none"> • Deletes monkeypox. • Clarifies that rapid reporting means immediately by the most rapid means, using consistent language between sections.
12VAC5-90-90		Those required to report	<ul style="list-style-type: none"> • Changes are proposed in wording for consistency between all the subsections, including clarification of rapid reporting. • The term 'broth' is clarified and Vibrio is added to the list of isolates that must be submitted to the Division of Consolidated Laboratory Services (DCLS) for further testing. • Laboratories suspecting a diagnosis of a select agent would submit an isolate to DCLS for confirmation. • Clarifications are added that local health departments can report to the state using the electronic surveillance system and that the state is responsible for notifying other states and the Centers for Disease Control and Prevention. • Clarification of what information may be released to the health department by schools, camps, and facilities on individuals has also been added.
12VAC5-90-100		Methods of disease control	<ul style="list-style-type: none"> • Proposes to update language to refer to the 20th edition (2015) of the <i>Control of Communicable Diseases Manual</i>.
12VAC5-90-110		Immunization	<ul style="list-style-type: none"> • States that required immunizations may be obtained from physicians, registered nurses, or other licensed professionals as authorized by the <i>Code of Virginia</i>.
12VAC5-90-280 through 12VAC5-		Reporting of dangerous microbes and pathogens	<ul style="list-style-type: none"> • Strikes section numbers and changes them to letters for consistency within the regulations; • Proposes to update references to the

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
90-360			<p><i>Code of Federal Regulations</i> to reflect changes in federal code section changes for select agent reporting;</p> <ul style="list-style-type: none"> Proposes to add language to clarify that select agent information is protected from release regardless of whether the information is submitted directly by laboratories or by federal agencies also holding the information. This is needed to ensure that terrorism-sensitive information is protected from access by potential terrorists seeking access to the materials.

1 Stage: Final

2 **DEPARTMENT OF HEALTH**

3 **Update Disease Reporting and Control Regulations**
4 **to Comply with Changes in Public Health Practice**

5 12VAC5-90-10

6 Part I

7 Definitions

8 12VAC5-90-10. Definitions.

9 The following words and terms when used in this chapter shall have the following meanings
10 unless the context clearly indicates otherwise:

11 ~~["Acute care hospital" means a hospital as defined in § 32.1-123 of the Code of Virginia that~~
12 ~~provides medical treatment for patients having an acute illness or injury or recovering from~~
13 ~~surgery.]~~

14 ~~["Adult intensive care unit" means a nursing care area that provides intensive observation,~~
15 ~~diagnosis, and therapeutic procedures for persons 18 years of age or more who are critically ill.~~
16 ~~Such units may also provide intensive care to pediatric patients. An intensive care unit excludes~~
17 ~~nursing areas that provide step-down, intermediate care, or telemetry only.]~~

18 "Affected area" means any part or the whole of the Commonwealth, which has been identified
19 as where persons reside, or may be located, who are known to have been exposed to or
20 infected with, or who are reasonably suspected to have been exposed to or infected with, a
21 communicable disease of public health threat. "Affected area" shall include, but not be limited
22 to, cities, counties, towns, and subsections of such areas, public and private property, buildings,
23 and other structures.

24 "Arboviral infection" means a viral illness that is transmitted by a mosquito, tick, or other
25 arthropod. This includes, but is not limited to, chikungunya [CHIK], dengue, eastern equine

1 encephalitis (EEE), LaCrosse encephalitis (LAC), St. Louis encephalitis (SLE), and West Nile
2 virus (WNV) infection.

3 "Board" means the State Board of Health.

4 "Cancer" means all carcinomas, sarcomas, melanomas, leukemias, and lymphomas excluding
5 localized basal and squamous cell carcinomas of the skin, except for lesions of the mucous
6 membranes.

7 "CDC" means the Centers for Disease Control and Prevention of the U.S. Department of Health
8 and Human Services.

9 [~~"Central line-associated bloodstream infection" means a primary bloodstream infection~~
10 ~~identified by laboratory tests, with or without clinical signs or symptoms, in a patient with a~~
11 ~~central line device, and meeting the current Centers for Disease Control and Prevention (CDC)~~
12 ~~CDC surveillance definition for laboratory-confirmed primary bloodstream infection.]~~

13 [~~"Central line device" means a vascular infusion device that terminates at or close to the heart or~~
14 ~~in one of the greater great vessels. The following are considered great vessels for the purpose~~
15 ~~of reporting central line infections and counting central line days: aorta, pulmonary artery,~~
16 ~~superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian~~
17 ~~veins, external iliac veins, and common femoral veins.]~~

18 "Child care center" means a child day center, child day program, family day home, family day
19 system, or registered family day home as defined by § 63.2-100 of the Code of Virginia, or a
20 similar place providing day care of children by such other name as may be applied.

21 "Clinic" means any facility, freestanding or associated with a hospital, that provides preventive,
22 diagnostic, therapeutic, rehabilitative, or palliative care or services to outpatients.

23 "Commissioner" means the State Health Commissioner or his duly designated officer or agent,
24 unless stated in a provision of these regulations that it applies to the State Health Commissioner
25 in his sole discretion.

1 "Communicable disease" means an illness due to an infectious agent or its toxic products which
2 is transmitted, directly or indirectly, to a susceptible host from an infected person, animal, or
3 arthropod or through the agency of an intermediate host or a vector or through the inanimate
4 environment.

5 "Communicable disease of public health significance" means an illness caused by a specific or
6 suspected infectious agent that may be transmitted directly or indirectly from one individual to
7 another. This includes but is not limited to infections caused by human immunodeficiency
8 viruses, bloodborne pathogens, and tubercle bacillus. The State Health Commissioner may
9 determine that diseases caused by other pathogens constitute communicable diseases of public
10 health significance.

11 "Communicable disease of public health threat" means an illness of public health significance,
12 as determined by the State Health Commissioner in accordance with these regulations, caused
13 by a specific or suspected infectious agent that may be reasonably expected or is known to be
14 readily transmitted directly or indirectly from one individual to another and has been found to
15 create a risk of death or significant injury or impairment; this definition shall not, however, be
16 construed to include human immunodeficiency viruses or the tubercle bacilli, unless used as a
17 bioterrorism weapon.

18 "Companion animal" means[, consistent with the provisions of § 3.2-6500,] any domestic or feral
19 dog, domestic or feral cat, nonhuman primate, guinea pig, hamster, rabbit not raised for human
20 food or fiber, exotic or native animal, reptile, exotic or native bird, or any feral animal or any
21 animal under the care, custody, or ownership of a person or any animal that is bought, sold,
22 traded, or bartered by any person. Agricultural animals, game species, or any animals regulated
23 under federal law as research animals shall not be considered companion animals for the
24 purpose of this regulation.

25 "Condition" means any adverse health event, such as a disease, an infection, a syndrome, or as
26 indicated by a procedure (including but not limited to the results of a physical exam, laboratory

1 test, or imaging interpretation) suggesting that an exposure of public health importance has
2 occurred.

3 "Contact" means a person or animal known to have been in such association with an infected
4 person or animal as to have had an opportunity of acquiring the infection.

5 "Contact services" means a broad array of services that are offered to persons with infectious
6 diseases and their contacts. Contact services include contact tracing, providing information
7 about current infections, developing risk reduction plans to reduce the chances of future
8 infections, and connecting to appropriate medical care and other services.

9 "Contact tracing" means the process by which an infected person or health department
10 employee notifies others that they may have been exposed to the infected person in a manner
11 known to transmit the infectious agent in question.

12 ["Coronavirus infection, severe" means suspected or confirmed infection with severe acute
13 respiratory syndrome (SARS)-associated coronavirus (SARS-CoV), Middle East respiratory
14 syndrome (MERS)-associated coronavirus (MERS-CoV), or another coronavirus causing a
15 severe acute illness.]

16 "Decontamination" means the use of physical or chemical means to remove, inactivate, or
17 destroy hazardous substances or organisms from a person, surface, or item to the point that
18 such substances or organisms are no longer capable of causing adverse health effects and the
19 surface or item is rendered safe for handling, use, or disposal.

20 "Department" means the State Department of Health[, also referred to as the Virginia
21 Department of Health (VDH)].

22 "Designee" or "designated officer or agent" means any person, or group of persons, designated
23 by the State Health Commissioner, to act on behalf of the commissioner or the board.

24 ~~"Ehrlichiosis/anaplasmosis"~~ "Ehrlichiosis/Anaplasmosis" means human infections caused by
25 Ehrlichia chaffeensis (formerly included in the category "human monocytic ehrlichiosis" or

1 "HME"), Ehrlichia ewingii or Anaplasma phagocytophilum (formerly included in the category
2 "human granulocytic ehrlichiosis" or "HGE").

3 "Epidemic" means the occurrence in a community or region of cases of an illness clearly in
4 excess of normal expectancy.

5 "Essential needs" means basic human needs for sustenance including but not limited to food,
6 water, clothing, and health care, (e.g., medications, therapies, testing, and durable medical
7 equipment).

8 "Exceptional circumstances" means the presence, as determined by the commissioner in his
9 sole discretion, of one or more factors that may affect the ability of the department to effectively
10 control a communicable disease of public health threat. Factors to be considered include but are
11 not limited to: (i) characteristics or suspected characteristics of the disease-causing organism or
12 suspected disease-causing organism such as virulence, routes of transmission, minimum
13 infectious dose, rapidity of disease spread, the potential for extensive disease spread, and the
14 existence and availability of demonstrated effective treatment; (ii) known or suspected risk
15 factors for infection; (iii) the potential magnitude of the effect of the disease on the health and
16 welfare of the public; and (iv) the extent of voluntary compliance with public health
17 recommendations. The determination of exceptional circumstances by the commissioner may
18 take into account the experience or results of investigation in Virginia, another state, or another
19 country.

20 "Foodborne outbreak" means two or more cases of a similar illness acquired through the
21 consumption of food contaminated with chemicals or an infectious agent or its toxic products.
22 Such illnesses include but are not limited to heavy metal intoxication, staphylococcal food
23 poisoning, botulism, salmonellosis, shigellosis, Clostridium perfringens food poisoning, hepatitis
24 A, and Shiga toxin-producing Escherichia coli O157:H7 infection.

25 "Healthcare-associated infection" (also known as nosocomial infection) means a localized or
26 systemic condition resulting from an adverse reaction to the presence of an infectious agent or

1 agents or its toxin or toxins that (i) occurs in a patient in a ~~healthcare~~ health care healthcare
2 setting (e.g., a hospital or outpatient clinic), (ii) was not found to be present or incubating at the
3 time of admission unless the infection was related to a previous admission to the same setting,
4 and (iii) if the setting is a hospital, meets the criteria for a specific infection site as defined by
5 CDC.

6 "Hepatitis C, acute" means the following clinical characteristics are met: (i) discrete onset of
7 symptoms indicative of viral hepatitis and (ii) jaundice or elevated serum aminotransferase
8 levels and the following laboratory criteria are met: (a) serum alanine aminotransferase levels
9 (ALT) greater than ~~400~~ 200 IU/L; (b) IgM anti-HAV negative (if done); (c) IgM anti-HBc
10 negative (if done); and (d) hepatitis C virus antibody (anti-HCV) ~~[screening test]~~ positive ~~[with a~~
11 ~~signal to cutoff ratio predictive of a true positive as determined for the particular assay as~~
12 ~~defined by CDC, HCV antibody positive by immunoblot (RIBA)],~~ [HCV antigen positive,] or HCV
13 RNA positive by nucleic acid test.

14 "Hepatitis C, chronic" means that the laboratory criteria specified in clauses (b), (c) and (d) listed
15 above for an acute case are met but clinical signs or symptoms of acute viral hepatitis are not
16 present and serum alanine aminotransferase (ALT) levels do not exceed ~~400~~ 200 IU/L. This
17 category will include cases that may be acutely infected but not symptomatic.

18 "Immunization" means a procedure that increases the protective response of an individual's
19 immune system to specified pathogens.

20 "Independent pathology laboratory" means a nonhospital or a hospital laboratory performing
21 surgical pathology, including fine needle aspiration biopsy and bone marrow specimen
22 examination services, which reports the results of such tests directly to physician offices, without
23 reporting to a hospital or accessioning the information into a hospital tumor registry.

24 "Individual" means a person or companion animal. When the context requires it, "person or
25 persons" shall be deemed to include any individual.

1 "Infection" means the entry and multiplication or persistence of a disease-causing organism
2 (prion, virus, bacteria, fungus, parasite, or ectoparasite) in the body of an individual. An infection
3 may be inapparent (i.e., without recognizable signs or symptoms but identifiable by laboratory
4 means) or manifest (clinically apparent).

5 "Influenza A, novel virus" means infection of a human with an influenza A virus subtype that is
6 different from currently circulating human influenza H1 and H3 viruses. Novel subtypes include
7 H2, H5, H7, and H9 subtypes or influenza H1 and H3 subtypes originating from a nonhuman
8 species.

9 "Invasive" means the organism is affecting a normally sterile site, including but not limited to
10 blood or cerebrospinal fluid.

11 "Investigation" means an inquiry into the incidence, prevalence, extent, source, mode of
12 transmission, causation of, and other information pertinent to a disease occurrence.

13 "Isolation" means the physical separation, including confinement or restriction of movement, of
14 an individual or individuals who are infected with, or are reasonably suspected to be infected
15 with, a communicable disease in order to prevent or limit the transmission of the communicable
16 disease to uninfected and unexposed individuals.

17 "Isolation, complete" means the full-time confinement or restriction of movement of an individual
18 or individuals infected with, or reasonably suspected to be infected with, a communicable
19 disease in order to prevent or limit the transmission of the communicable disease to uninfected
20 and unexposed individuals.

21 "Isolation, modified" means a selective, partial limitation of freedom of movement or actions of
22 an individual or individuals infected with, or reasonably suspected to be infected with, a
23 communicable disease. Modified isolation is designed to meet particular situations and includes
24 but is not limited to the exclusion of children from school, the prohibition or restriction from
25 engaging in a particular occupation or using public or mass transportation, or requirements for
26 the use of devices or procedures intended to limit disease transmission.

1 "Isolation, protective" means the physical separation of a susceptible individual or individuals
2 not infected with, or not reasonably suspected to be infected with, a communicable disease from
3 an environment where transmission is occurring, or is reasonably suspected to be occurring, in
4 order to prevent the individual or individuals from acquiring the communicable disease.

5 "Laboratory" as used herein means a clinical laboratory that examines materials derived from
6 the human body for the purpose of providing information on the diagnosis, prevention, or
7 treatment of disease.

8 "Laboratory director" means any person in charge of supervising a laboratory conducting
9 business in the Commonwealth of Virginia.

10 "Law-enforcement agency" means any sheriff's office, police department, adult or youth
11 correctional officer, or other agency or department that employs persons who have law-
12 enforcement authority that is under the direction and control of the Commonwealth or any local
13 governing body. "Law-enforcement agency" shall include, by order of the Governor, the Virginia
14 National Guard.

15 [~~"Lead, elevated blood levels" means a confirmed blood level greater than or equal to] 10
16 micrograms of lead per deciliter ($\mu\text{g}/\text{dL}$) of whole blood in a child or children 15 years of age and
17 younger, a venous blood lead level greater than or equal to 25 $\mu\text{g}/\text{dL}$ in a person older than 15
18 years of age, or such lower blood lead level as may be recommended for individual intervention
19 by the department or the Centers for Disease Control and Prevention [the reference value
20 established by the CDC. In 2012, the reference value was 5 $\mu\text{g}/\text{dL}$ in children and 10 $\mu\text{g}/\text{dL}$ for
21 persons older than 15 years of age.]~~

22 ["Lead, reportable levels" means any detectable blood lead level in children 15 years of age and
23 younger and levels greater than or equal to 5 $\mu\text{g}/\text{dL}$ in a person older than 15 years of age.]

24 "Least restrictive" means the minimal limitation of the freedom of movement and communication
25 of an individual while under an order of isolation or an order of quarantine that also effectively
26 protects unexposed and susceptible individuals from disease transmission.

1 "Medical care facility" means any hospital or nursing home licensed in the Commonwealth, or
2 any hospital operated by or contracted to operate by an entity of the United States government
3 or the Commonwealth of Virginia.

4 "Midwife" means any person who is licensed as a nurse midwife by the Virginia Boards of
5 Nursing and Medicine or who is licensed by the Board of Medicine as a certified professional
6 midwife.

7 "National Healthcare Safety Network-~~(NHSN)~~ or "NHSN" means a surveillance system created
8 by the CDC for accumulating, exchanging, and integrating relevant information on infectious
9 adverse events associated with ~~healthcare~~ health care delivery.

10 "Nucleic acid detection" means laboratory testing of a clinical specimen to determine the
11 presence of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) specific for an infectious
12 agent using any method, including hybridization, sequencing, or amplification such as
13 polymerase chain reaction.

14 "Nurse" means any person licensed as a professional nurse or as a licensed practical nurse by
15 the Virginia Board of Nursing.

16 "Occupational outbreak" means a cluster of illness or disease that is indicative of a work-related
17 exposure. Such conditions include but are not limited to silicosis, asbestosis, byssinosis,
18 pneumoconiosis, and tuberculosis.

19 "Outbreak" means the occurrence of more cases of a disease than expected.

20 "Period of communicability" means the time or times during which the etiologic agent may be
21 transferred directly or indirectly from an infected person to another person, or from an infected
22 animal to a person.

23 "Physician" means any person licensed to practice medicine or osteopathy by the Virginia Board
24 of Medicine.

25 "Quarantine" means the physical separation, including confinement or restriction of movement,
26 of an individual or individuals who are present within an affected area or who are known to have

1 been exposed, or may reasonably be suspected to have been exposed, to a communicable
2 disease and who do not yet show signs or symptoms of infection with the communicable
3 disease in order to prevent or limit the transmission of the communicable disease of public
4 health threat to unexposed and uninfected individuals.

5 "Quarantine, complete" means the full-time confinement or restriction of movement of an
6 individual or individuals who do not have signs or symptoms of infection but may have been
7 exposed, or may reasonably be suspected to have been exposed, to a communicable disease
8 of public health threat in order to prevent the transmission of the communicable disease of
9 public health threat to uninfected individuals.

10 "Quarantine, modified" means a selective, partial limitation of freedom of movement or actions
11 of an individual or individuals who do not have signs or symptoms of the infection but have been
12 exposed to, or are reasonably suspected to have been exposed to, a communicable disease of
13 public health threat. Modified quarantine may be designed to meet particular situations and
14 includes but is not limited to limiting movement to the home, work, ~~and/or~~ or one or more other
15 locations, the prohibition or restriction from using public or mass transportation, or requirements
16 for the use of devices or procedures intended to limit disease transmission.

17 "Reportable disease" means an illness due to a specific toxic substance, occupational
18 exposure, or infectious agent, which affects a susceptible individual, either directly, as from an
19 infected animal or person, or indirectly through an intermediate host, vector, or the environment,
20 as determined by the board.

21 ~~["SARS" means severe acute respiratory syndrome (SARS)-associated coronavirus (SARS-~~
22 ~~CoV) disease, Middle East respiratory syndrome (MERS)-associated coronavirus (MERS-CoV)~~
23 ~~disease, or another coronavirus causing a severe acute illness.]~~

24 "School" means (i) any public school from kindergarten through grade 12 operated under the
25 authority of any locality within the Commonwealth; (ii) any private or ~~[parochial~~ religious] school
26 that offers instruction at any level or grade from kindergarten through grade 12; (iii) any private

1 or ~~parochial~~ religious nursery school or preschool, or any private or ~~parochial~~ religious child
2 care center licensed by the Commonwealth; ~~and (iv) any preschool handicap classes or Head~~
3 ~~Start classes~~].

4 "Serology" means the testing of blood, serum, or other body fluids for the presence of antibodies
5 or other markers of an infection or disease process.

6 "Surveillance" means the ongoing systematic collection, analysis, and interpretation of outcome-
7 specific data for use in the planning, implementation, and evaluation of public health practice. A
8 surveillance system includes the functional capacity for data analysis as well as the timely
9 dissemination of these data to persons who can undertake effective prevention and control
10 activities.

11 "Susceptible individual" means a person or animal who is vulnerable to or potentially able to
12 contract a disease or condition. Factors that affect an individual's susceptibility include but are
13 not limited to physical characteristics, genetics, previous or chronic exposures, chronic
14 conditions or infections, immunization history, or use of medications.

15 "Toxic substance" means any substance, including any raw materials, intermediate products,
16 catalysts, final products, or by-products of any manufacturing operation conducted in a
17 commercial establishment, that has the capacity, through its physical, chemical or biological
18 properties, to pose a substantial risk of death or impairment either immediately or over time, to
19 the normal functions of humans, aquatic organisms, or any other animal but not including any
20 pharmaceutical preparation which deliberately or inadvertently is consumed in such a way as to
21 result in a drug overdose.

22 "Tubercle bacilli" means disease-causing organisms belonging to the Mycobacterium
23 tuberculosis complex and includes Mycobacterium tuberculosis, Mycobacterium bovis, and
24 Mycobacterium africanum or other members as may be established by the commissioner.

25 "Tuberculin skin test (TST)" means a test for demonstrating infection with tubercle bacilli,
26 performed according to the Mantoux method, in which 0.1 ml of 5 TU strength tuberculin purified

1 protein derivative (PPD) is injected intradermally on the volar surface of the arm. Any reaction is
2 observed 48-72 hours after placement and palpable induration is measured across the diameter
3 transverse to the long axis of the arm. The measurement of the indurated area is recorded in
4 millimeters and the significance of the measured induration is based on existing national and
5 department guidelines.

6 "Tuberculosis" means a disease caused by tubercle bacilli.

7 "Tuberculosis, active disease" (also "active tuberculosis disease" and "active TB disease"), as
8 defined by § 32.1-49.1 of the Code of Virginia, means a disease caused by an airborne
9 microorganism and characterized by the presence of either (i) a specimen of sputum or other
10 bodily fluid or tissue that has been found to contain tubercle bacilli as evidenced by culture or
11 nucleic acid amplification, including preliminary identification by rapid methodologies; (ii) a
12 specimen of sputum or other bodily fluid or tissue that is suspected to contain tubercle bacilli as
13 evidenced by smear, and where sufficient clinical and radiographic evidence of active
14 tuberculosis disease is present as determined by a physician licensed to practice medicine in
15 Virginia; or (iii) sufficient clinical and radiographic evidence of active tuberculosis disease as
16 determined by the commissioner is present, but a specimen of sputum or other bodily fluid or
17 tissue containing, or suspected of containing, tubercle bacilli is unobtainable.

18 "Tuberculosis infection in children age ~~less than 4~~ ≤4 years" means a significant reaction
19 resulting from a tuberculin skin test (TST) or other approved test for latent infection without
20 clinical or radiographic evidence of active tuberculosis disease, in children from birth up to their
21 fourth birthday.

22 "Vaccinia, disease or adverse event" means vaccinia infection or serious or unexpected events
23 in persons who received the smallpox vaccine or their contacts, including but not limited to
24 bacterial infections, eczema vaccinatum, erythema multiforme, generalized vaccinia,
25 progressive vaccinia, inadvertent inoculation, post-vaccinial encephalopathy or
26 encephalomyelitis, ocular vaccinia, and fetal vaccinia.

1 "Waterborne outbreak" means two or more cases of a similar illness acquired through the
2 ingestion of or other exposure to water contaminated with chemicals or an infectious agent or its
3 toxic products. Such illnesses include but are not limited to giardiasis, viral gastroenteritis,
4 cryptosporidiosis, hepatitis A, cholera, and shigellosis. A single case of laboratory-confirmed
5 primary amebic meningoencephalitis or of waterborne chemical poisoning is considered an
6 outbreak.

7 12VAC5-90-50

8 12VAC5-90-50. ~~Applicability. (Repealed.)~~

9 ~~A. This chapter has general application throughout the Commonwealth.~~

10 ~~B. The provisions of the Virginia Administrative Process Act, which is codified as Chapter 40 (§~~
11 ~~2.2-4000 et seq.) of Title 2.2 of the Code of Virginia shall govern the adoption, amendment,~~
12 ~~modification, and revision of this chapter, and the conduct of all proceedings and appeals~~
13 ~~hereunder. All hearings on such regulations shall be conducted in accordance with § 2.2-~~
14 ~~4007.01 of the Code of Virginia.~~

15 12VAC5-90-80

16 Part III

17 Reporting of Disease

18 12VAC5-90-80. ~~Reportable disease list~~ Lists of diseases that shall be reported.

19 A. Reportable disease list. The board declares suspected or confirmed cases of the following
20 named diseases, toxic effects, and conditions to be reportable by the persons enumerated in
21 12VAC5-90-90. Conditions identified by an asterisk (*) require immediate communication to the
22 local health department by the most rapid means available upon suspicion or confirmation, as
23 defined in subsection C of this section. Other conditions should be reported within three days of
24 suspected or confirmed diagnosis.

25 Acquired immunodeficiency syndrome (AIDS)

26 Amebiasis

- 1 *Anthrax
- 2 Arboviral infections (e.g., [CHIK.] dengue, EEE, LAC, SLE, WNV)
- 3 Babesiosis
- 4 *Botulism
- 5 *Brucellosis
- 6 Campylobacteriosis
- 7 Chancroid
- 8 Chickenpox (Varicella)
- 9 Chlamydia trachomatis infection
- 10 *Cholera
- 11 [*Coronavirus infection, severe]
- 12 Creutzfeldt-Jakob disease if <55 years of age
- 13 Cryptosporidiosis
- 14 Cyclosporiasis
- 15 *Diphtheria
- 16 *Disease caused by an agent that may have been used as a weapon
- 17 Ehrlichiosis/Anaplasmosis
- 18 Escherichia coli infection, Shiga toxin-producing
- 19 Giardiasis
- 20 Gonorrhea
- 21 Granuloma inguinale
- 22 *Haemophilus influenzae infection, invasive
- 23 Hantavirus pulmonary syndrome
- 24 Hemolytic uremic syndrome (HUS)
- 25 *Hepatitis A
- 26 Hepatitis B (acute and chronic)

- 1 Hepatitis C (acute and chronic)
- 2 Hepatitis, other acute viral
- 3 Human immunodeficiency virus (HIV) infection
- 4 Influenza
- 5 *Influenza-associated deaths in children <18 years of age
- 6 Lead, [~~elevated blood levels~~ reportable levels]
- 7 Legionellosis
- 8 Leprosy (~~Hansen~~ Hansen's disease)
- 9 Leptospirosis
- 10 Listeriosis
- 11 Lyme disease
- 12 Lymphogranuloma venereum
- 13 Malaria
- 14 *Measles (Rubeola)
- 15 *Meningococcal disease
- 16 ~~*Monkeypox~~
- 17 Mumps
- 18 Ophthalmia neonatorum
- 19 *Outbreaks, all (including but not limited to foodborne, ~~healthcare-associated~~ health care-
- 20 associated healthcare-associated], occupational, toxic substance-related, and waterborne)
- 21 *Pertussis
- 22 *Plague
- 23 *Poliovirus infection, including poliomyelitis
- 24 *Psittacosis
- 25 *Q fever
- 26 *Rabies, human and animal

- 1 Rabies treatment, post-exposure
- 2 *Rubella, including congenital rubella syndrome
- 3 Salmonellosis
- 4 [~~*Severe acute respiratory syndrome (SARS), including any coronavirus causing a severe acute~~
- 5 illness]
- 6 Shigellosis
- 7 *Smallpox (Variola)
- 8 Spotted fever rickettsiosis
- 9 Staphylococcus aureus infection, vancomycin-intermediate or vancomycin-resistant
- 10 Streptococcal disease, Group A, invasive or toxic shock
- 11 Streptococcus pneumoniae infection, invasive, in children <5 years of age
- 12 Syphilis (report *primary and *secondary syphilis by rapid means)
- 13 Tetanus
- 14 Toxic substance-related illness
- 15 Trichinosis (Trichinellosis)
- 16 *Tuberculosis, active disease
- 17 Tuberculosis infection in children <4 years of age
- 18 *Tularemia
- 19 *Typhoid/Paratyphoid fever
- 20 *Unusual occurrence of disease of public health concern
- 21 *Vaccinia, disease or adverse event
- 22 *Vibrio infection
- 23 *Viral hemorrhagic fever
- 24 *Yellow fever
- 25 Yersiniosis
- 26 B. Conditions reportable by directors of laboratories.

1 Conditions identified by an asterisk (*) require immediate communication to the local health
2 department by the most rapid means available upon suspicion or confirmation, as defined in
3 subsection C of this section. Other conditions should be reported within three days of suspected
4 or confirmed diagnosis.

5 Amebiasis - by microscopic examination, culture, antigen detection, nucleic acid detection, or
6 serologic results consistent with recent infection

7 *Anthrax - by culture, antigen detection [~~or~~], nucleic acid detection[, or serologic results
8 consistent with recent infection]

9 Arboviral infection - by culture, antigen detection, nucleic acid detection, or serologic results
10 consistent with recent infection

11 Babesiosis - by culture, antigen detection, nucleic acid detection, [microscopic examination,]or
12 serologic results consistent with recent infection

13 *Botulism - by culture, nucleic acid detection, or identification of ~~toxin~~ neurotoxin in a clinical
14 specimen

15 *Brucellosis - by culture, antigen detection, nucleic acid detection, or serologic results consistent
16 with recent infection

17 Campylobacteriosis - by culture[, or culture-independent diagnostic test (CIDT) (i.e.,] antigen
18 detection[, or nucleic acid detection]). [For CIDT, also] submit all [available] culture results
19 (positive or negative) associated with a positive [antigen detection test result].

20 Chancroid - by culture, antigen detection, or nucleic acid detection

21 Chickenpox (~~varicella~~) (Varicella) - by culture, antigen detection, nucleic acid detection, or
22 serologic results consistent with recent infection

23 Chlamydia trachomatis infection - by culture, antigen detection, nucleic acid detection or, for
24 lymphogranuloma venereum, serologic results consistent with recent infection

25 *Cholera - by culture[, antigen detection, nucleic acid detection,] or serologic results consistent
26 with recent infection

1 [*Coronavirus infection, severe - by culture, nucleic acid detection, or serologic results
2 consistent with recent infection]

3 Creutzfeldt-Jakob disease if <55 years of age by histopathology in patients under the age of 55
4 years

5 Cryptosporidiosis - by microscopic examination, antigen detection, or nucleic acid detection

6 Cyclosporiasis - by microscopic examination or nucleic acid detection

7 *Diphtheria - by culture or histopathology

8 Ehrlichiosis/Anaplasmosis - by culture, nucleic acid detection, [microscopic examination,] or
9 serologic results consistent with recent infection

10 Escherichia coli infection, Shiga toxin-producing - by culture of E. coli O157 or other Shiga toxin-
11 producing E. coli, Shiga toxin detection (e.g., [nucleic acid detection, by] EIA), or [nucleic acid
12 detection serologic results consistent with recent infection]

13 Giardiasis - by microscopic examination ~~or,~~ antigen detection, or nucleic acid detection

14 Gonorrhea - by microscopic examination of a urethral smear [specimen] (males only)] or
15 endocervical smear (females only,)] culture, antigen detection, or nucleic acid detection. Include
16 available antimicrobial susceptibility findings in report.

17 *Haemophilus influenzae infection, invasive - by culture, antigen detection, or nucleic acid
18 detection from a normally sterile site

19 Hantavirus pulmonary syndrome - by antigen detection (immunohistochemistry), nucleic acid
20 detection, or serologic results consistent with recent infection

21 *Hepatitis A - by detection of IgM antibodies

22 Hepatitis B (acute and chronic) - by detection of HBsAg, HBeAg, or IgM antibodies or nucleic
23 acid detection. For any reportable hepatitis finding, submit all available results from the hepatitis
24 panel. [Submit all findings for hepatitis B testing in children younger than two years of age.]

25 Hepatitis C (acute and chronic) - by hepatitis C virus antibody (anti-HCV) [screening test]
26 positive [with a signal-to-cutoff ratio predictive of a true positive as determined for the particular

1 assay as defined by CDC, HCV antibody positive by immunoblot (RIBA), [HCV antigen
2 positive,] or HCV RNA positive by nucleic acid test. For all hepatitis C patients, also report
3 available results of serum alanine aminotransferase (ALT)₇ [~~anti-HAV IgM, anti-HBc IgM, and~~
4 ~~HBsAg. For any reportable hepatitis finding, submit~~] and all available results from the hepatitis
5 panel.

6 Hepatitis, other acute viral – any finding indicative of acute infection with hepatitis D, E, or other
7 cause of viral hepatitis. For any reportable hepatitis finding, submit all available results from the
8 hepatitis panel.

9 Human immunodeficiency virus (HIV) infection - by culture, antigen detection, nucleic acid
10 detection, or detection of antibody ~~confirmed with a supplemental test.~~ For HIV-infected
11 patients, report all results of CD4 and HIV viral load tests [including undetectable viral loads.
12 For HIV-infected patients, report] and all HIV genetic [nucleotide] sequence data associated
13 with HIV drug resistance tests [by electronic submission]. For children [from birth to] [less than]
14 three years of age, report all tests regardless of the test findings (e.g., negative or positive).

15 Influenza - by culture, antigen detection by direct fluorescent antibody (DFA), or nucleic acid
16 detection

17 Lead, [~~elevated blood levels reportable levels~~] – [~~by blood lead level greater than or equal to~~] 10
18 ~~µg/dL in children ages 0-15 years, or greater than or equal to 25 µg/dL in persons older than 15~~
19 ~~years of age [the reference value established by CDC. The reference value established in 2012~~
20 ~~was 5 µg/dL in children and 10 µg/dL in persons older than 15 years of age.] [by any detectable~~
21 ~~blood lead level in children ages 0-15 years or levels greater than or equal to 5 µg/dL in persons~~
22 ~~older than 15 years of age.]~~

23 Legionellosis - by culture, antigen detection (including urinary antigen), nucleic acid detection, or
24 serologic results consistent with recent infection

25 Leptospirosis - by culture, microscopic examination by dark field microscopy, nucleic acid
26 detection, or serologic results consistent with recent infection

1 Listeriosis - by culture [from a normally sterile site. If associated with miscarriage or stillbirth, by
2 culture from placental or fetal tissue]

3 Lyme disease - by culture, antigen detection, or detection of antibody confirmed with a
4 supplemental test

5 Malaria - by microscopic examination, antigen detection, or nucleic acid detection

6 *Measles (~~rubeola~~) (Rubeola) - by culture, antigen detection, nucleic acid detection, or serologic
7 results consistent with recent infection

8 *Meningococcal disease - by culture[, nucleic acid detection,] or antigen detection from a
9 normally sterile site

10 ~~*Monkeypox – by culture or nucleic acid detection~~

11 Mumps - by culture, nucleic acid detection, or serologic results consistent with recent infection

12 *Mycobacterial diseases - (See 12VAC5-90-225 B) Report any of the following:

13 1. Acid fast bacilli by microscopic examination;

14 2. Mycobacterial identification - preliminary and final identification by culture or nucleic acid
15 detection;

16 3. Drug susceptibility test results for M. tuberculosis.

17 *Pertussis - by culture, antigen detection, [~~or~~] nucleic acid detection[, or serologic results
18 consistent with recent infection]

19 *Plague - by culture, antigen detection, nucleic acid detection, or serologic results consistent
20 with recent infection

21 *Poliovirus infection - by culture

22 *Psittacosis - by culture, antigen detection, nucleic acid detection, or serologic results consistent
23 with recent infection

24 *Q fever - by culture, antigen detection, nucleic acid detection, [immunohistochemical
25 methods,]or serologic results consistent with recent infection

1 *Rabies, human and animal - by culture, antigen detection by direct fluorescent antibody test,
2 nucleic acid detection, or, for humans only, serologic results consistent with recent infection
3 *Rubella - by culture, nucleic acid detection, or serologic results consistent with recent infection
4 Salmonellosis - by culture[,] [or] antigen detection [, or nucleic acid detection]
5 ~~[*Severe acute respiratory syndrome, including any coronavirus causing a severe acute illness -~~
6 ~~by culture, nucleic acid detection, or serologic results consistent with recent infection]~~
7 Shigellosis - by culture[,] [or] antigen detection [, or nucleic acid detection]
8 *Smallpox (~~variola~~) (Variola) - by culture or nucleic acid detection
9 Spotted fever rickettsiosis - by culture, antigen detection (including immunohistochemical
10 staining), nucleic acid detection, or serologic results consistent with recent infection
11 Staphylococcus aureus infection, resistant, as defined below:;
12 1. ~~Methicillin-resistant - by antimicrobial susceptibility testing of a Staphylococcus aureus~~
13 ~~isolate, with a susceptibility result indicating methicillin resistance, cultured from a normally~~
14 ~~sterile site~~
15 2. Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection - by
16 antimicrobial susceptibility testing of a Staphylococcus aureus isolate, with a vancomycin
17 susceptibility result of intermediate or resistant, cultured from a clinical specimen. Include
18 available antimicrobial susceptibility findings in report.
19 Streptococcal disease, Group A, invasive or toxic shock – [for invasive disease,] by culture from
20 a normally sterile site; [for streptococcal toxic shock, by culture from any body site]
21 Streptococcus pneumoniae infection, invasive, in children <5 years of age - by culture from a
22 normally sterile site in a child under the age of five years
23 *Syphilis – by ~~[microscopic examination (including dark field),]~~ [darkfield microscopy,] antigen
24 detection ~~[(including direct fluorescent antibody),]~~ [nucleic acid detection,] or serology by either
25 treponemal or nontreponemal methods

1 Toxic substance-related illness - by blood or urine laboratory findings above the normal range,
2 including but not limited to heavy metals, pesticides, and industrial-type solvents and gases.
3 When applicable and available, report speciation of metals when blood or urine levels are
4 elevated in order to differentiate the chemical species (elemental, organic, or inorganic).
5 Trichinosis (~~trichinellosis~~) (Trichinellosis) - by microscopic examination of a muscle biopsy or
6 serologic results consistent with recent infection
7 *Tularemia - by culture, antigen detection, nucleic acid detection, or serologic results consistent
8 with recent infection
9 *Typhoid/Paratyphoid fever - by culture[, antigen detection, or nucleic acid detection]
10 *Vaccinia, disease or adverse event - by culture or nucleic acid detection
11 *Vibrio infection – [~~by culture. Include Photobacterium damsela and Grimontia hollisae as well~~
12 as Vibrio species. isolation of any species of the family Vibrionaceae (other than toxigenic Vibrio
13 cholera O1 or O139, which are reportable as cholera) from a clinical specimen by culture,
14 antigen detection, or nucleic acid detection]
15 *Viral hemorrhagic fever - by culture, antigen detection (including immunohistochemical
16 staining), nucleic acid detection, or serologic results consistent with recent infection
17 *Yellow fever - by culture, antigen detection, nucleic acid detection, or serologic results
18 consistent with recent infection
19 Yersiniosis - by culture, nucleic acid detection, or serologic results consistent with recent
20 infection
21 C. Reportable diseases requiring rapid communication. Certain of the diseases in the list of
22 reportable diseases, because of their extremely contagious nature or their potential for greater
23 harm, or both, require immediate identification and control. Reporting of persons confirmed or
24 suspected of having these diseases, listed below, shall be made immediately by the most rapid
25 means available, preferably that of telecommunication (e.g., by telephone, telephone
26 transmitted facsimile, pagers, etc.) to the local health director or other professional employee of

- 1 ~~the~~ department. (These same diseases are also identified by an asterisk (*) in ~~subsection A and~~
- 2 ~~subsection B~~ subsections A and B, where applicable, of this section.)
- 3 Anthrax
- 4 Botulism
- 5 Brucellosis
- 6 Cholera
- 7 [Coronavirus infection, severe]
- 8 Diphtheria
- 9 Disease caused by an agent that may have been used as a weapon
- 10 Haemophilus influenzae infection, invasive
- 11 Hepatitis A
- 12 Influenza-associated deaths in children <18 years of age
- 13 Influenza A, novel virus
- 14 Measles (Rubeola)
- 15 Meningococcal disease
- 16 ~~Monkeypox~~
- 17 Outbreaks, all
- 18 Pertussis
- 19 Plague
- 20 Poliovirus infection, including poliomyelitis
- 21 Psittacosis
- 22 Q fever
- 23 Rabies, human and animal
- 24 Rubella, including congenital rubella syndrome
- 25 ~~[Severe acute respiratory syndrome (SARS), including any coronavirus causing a severe acute~~
- 26 ~~illness]~~

- 1 Smallpox (Variola)
- 2 Syphilis, primary and secondary
- 3 Tuberculosis, active disease
- 4 Tularemia
- 5 ~~*Typhoid/Paratyphoid~~ Typhoid/Paratyphoid fever
- 6 Unusual occurrence of disease of public health concern
- 7 Vaccinia, disease or adverse event
- 8 Vibrio infection
- 9 Viral hemorrhagic fever
- 10 Yellow fever

11 D. Toxic substance-related illnesses. All toxic substance-related illnesses, including pesticide
12 and heavy metal poisoning or illness resulting from exposure to an occupational dust or fiber or
13 radioactive substance, shall be reported.

14 If such illness is verified or suspected and presents an emergency or a serious threat to public
15 health or safety, the report of such illness shall be ~~by rapid communication as in subsection C of~~
16 ~~this section~~ made immediately by the most rapid means available[, preferably by telephone].

17 E. Outbreaks. The occurrence of outbreaks or clusters of any illness which may represent a
18 group expression of an illness which may be of public health concern shall be reported to the
19 local health department immediately by the most rapid means available[, preferably by
20 telephone].

21 F. Unusual or ill-defined diseases or emerging or reemerging pathogens. Unusual or emerging
22 conditions of public health concern shall be reported to the local health department immediately
23 by the most rapid means available[, preferably by telephone]. In addition, the commissioner or
24 his designee may establish surveillance systems for diseases or conditions that are not on the
25 list of reportable diseases. Such surveillance may be established to identify cases (delineate the
26 magnitude of the situation), to identify the mode of transmission and risk factors for the disease,

1 and to identify and implement appropriate action to protect public health. Any person reporting
2 information at the request of the department for special surveillance or other epidemiological
3 studies shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.
4 12VAC5-90-90
5 12VAC5-90-90. Those required to report.
6 A. Physicians. Each physician who treats or examines any person who is suffering from or who
7 is suspected of having a reportable disease or condition shall report that person's name,
8 address, age, date of birth, race, sex, and pregnancy status for females; name of disease
9 diagnosed or suspected; the date of onset of illness; available laboratory tests and results; and
10 the name, address, and telephone number of the physician and medical facility where the
11 examination was made, except that influenza should be reported by number of cases only (and
12 type of influenza, if available). Reports are to be made to the local health department serving
13 the jurisdiction where the physician practices. A physician may designate someone to report on
14 his behalf, but the physician remains responsible for ensuring that the appropriate report is
15 made. Any physician, designee, or organization making such report as authorized herein shall
16 be immune from liability as provided by § 32.1-38 of the Code of Virginia.
17 Such reports shall be made on a ~~form to be provided by the department (Form Epi-1)~~ Form Epi-
18 1, a computer generated printout containing the data items requested on Form Epi-1, or a
19 ~~Centers for Disease Control and Prevention (CDC)~~ CDC [or VDH] surveillance form that
20 provides the same information and shall be made within three days of the suspicion or
21 confirmation of disease ~~unless the disease in question requires rapid reporting under 12VAC5-~~
22 ~~90-80-C~~ except that those identified in 12VAC5-90-80 C shall be reported immediately by the
23 most rapid means available[, preferably by telephone] to the local health department serving the
24 jurisdiction in which the facility is located. Reporting may be done by means of secure electronic
25 transmission upon agreement of the physician and the department.

1 Pursuant to ~~§ 32.1-49.1 of the Code of Virginia~~, additional Additional elements are required to
2 be reported for individuals with confirmed or suspected active tuberculosis disease. Refer to
3 Part X (12VAC5-90-225 et seq.) for details on these requirements.

4 B. Directors of laboratories. [~~Any person who is in charge of a laboratory conducting business in~~
5 ~~the Commonwealth~~ Laboratory directors] shall report any laboratory examination of any clinical
6 specimen, whether performed in-house or referred to an out-of-state laboratory, which yields
7 evidence, by the laboratory method(s) indicated or any other confirmatory test, of a disease
8 listed in 12VAC5-90-80 B.

9 Each report shall give the source of the specimen and the laboratory method and result; the
10 name, address, age, date of birth, race, sex, and pregnancy status for females (if known) of the
11 person from whom the specimen was obtained; and the name, address, and telephone number
12 of the physician [~~for whom~~ at whose request] and medical facility ~~for whom~~ at which the
13 examination was made. When the influenza virus is isolated, the type should be reported, if
14 available. Reports shall be made within three days of identification of evidence of disease,
15 except that those identified ~~by an asterisk in 12VAC5-90-80 C~~ shall be reported immediately by
16 the most rapid means available, [preferably by telephone] to the local health department
17 serving the jurisdiction in which the laboratory is located. Reports shall be made on Form Epi-1
18 or on the laboratory's own form if it includes the required information. Computer generated
19 reports containing the required information may be submitted. Reporting may be done by means
20 of secure electronic transmission upon agreement of the laboratory director and the department.
21 [Reports of HIV genetic nucleotide sequence data associated with HIV drug resistance tests
22 must be submitted electronically.] Any person making such report as authorized herein shall be
23 immune from liability as provided by § 32.1-38 of the Code of Virginia.

24 A laboratory identifying evidence of any of the following conditions shall notify the local health
25 department of the positive culture or other positive test result within the timeframes specified in
26 12VAC5-90-80 and submit the initial isolate or other initial specimen to the ~~Virginia~~ Division of

- 1 Consolidated Laboratory Services (~~DCLS~~) within seven days of identification. All specimens
- 2 must be identified with the patient and physician information required in this subsection.
- 3 Anthrax
- 4 [Botulism]
- 5 Brucellosis
- 6 Cholera
- 7 Diphtheria
- 8 E. coli infection, Shiga toxin-producing. (Laboratories that use a Shiga toxin EIA methodology
- 9 but do not perform simultaneous culture for Shiga toxin-producing E. coli should forward all
- 10 positive stool specimens or positive ~~broth cultures~~ enrichment broths to ~~DCLS~~ the Division of
- 11 Consolidated Laboratory Services for confirmation and further characterization.)
- 12 Haemophilus influenzae infection, invasive
- 13 Human immunodeficiency virus (HIV) (Submit all [~~remnant HIV diagnostic sera available~~
- 14 remnant sera from HIV positive diagnostic tests] to the Division of Consolidated Laboratory
- 15 Services or other laboratory designated by the department for HIV recency testing.)
- 16 Influenza A, novel virus
- 17 Listeriosis
- 18 Meningococcal disease
- 19 Pertussis
- 20 Plague
- 21 Poliovirus infection
- 22 Q fever
- 23 Salmonellosis
- 24 Shigellosis
- 25 Streptococcal disease, Group A, invasive

1 Tuberculosis (A laboratory identifying Mycobacterium tuberculosis complex (see 12VAC5-90-
2 225) shall submit a representative and viable sample of the initial culture to ~~DCLS~~ the Division
3 of Consolidated Laboratory Services or other laboratory designated by the board to receive
4 such specimen.)

5 [Tularemia]

6 Typhoid/Paratyphoid fever

7 Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection

8 Vibrio infection, including infections due to Photobacterium damsela and Grimontia hollisae

9 Yersiniosis

10 Other diseases as may be requested by the health department

11 When a clinical specimen yields evidence indicating the presence of a select agent or toxin as
12 defined by federal regulations in 42 CFR Part 73, the person in charge of the laboratory shall
13 contact the Division of Consolidated Laboratory Services and arrange to forward an isolate for
14 confirmation. If a select agent or toxin has been confirmed in a clinical specimen, the laboratory
15 director shall consult with Division of Consolidated Laboratory Services or CDC regarding
16 isolate transport or destruction.

17 Laboratories operating within a medical care facility shall be considered to be in compliance with
18 the requirement to notify the local health department when the director of that medical care
19 facility assumes the reporting responsibility; however, laboratories are still required to submit
20 isolates to ~~DCLS~~ the Division of Consolidated Laboratory Services or other designated
21 laboratory as noted ~~above~~ in this subsection.

22 C. Persons in charge of a medical care facility. Any person in charge of a medical care facility
23 shall make a report to the local health department serving the jurisdiction where the facility is
24 located of the occurrence in or admission to the facility of a patient with a reportable disease
25 listed in 12VAC5-90-80 A unless he has evidence that the occurrence has been reported by a
26 physician. Any person making such report as authorized herein shall be immune from liability as

1 provided by § 32.1-38 of the Code of Virginia. The requirement to report shall include all
2 inpatient, outpatient, and emergency care departments within the medical care facility. Such
3 report shall contain the patient's name, address, age, date of birth, race, sex, and pregnancy
4 status for females; name of disease being reported; [available laboratory tests and results;] the
5 date of admission; hospital chart number; date expired (when applicable); and attending
6 physician. Influenza should be reported by number of cases only (and type of influenza, if
7 available). Reports shall be made within three days of the suspicion or confirmation of disease
8 ~~unless the disease in question requires rapid reporting under 12VAC5-90-80 C and~~ except that
9 those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means
10 available[, preferably by telephone] to the local health department serving the jurisdiction in
11 which the facility is located. Reports shall be made on Form Epi-1, a computer generated
12 printout containing the data items requested on Form Epi-1, or a ~~Centers for Disease Control~~
13 ~~and Prevention (CDC) CDC [or VDH]~~ surveillance form that provides the same information.
14 Reporting may be done by means of secure electronic transmission upon agreement of the
15 medical care facility and the department.

16 A person in charge of a medical care facility may assume the reporting responsibility on behalf
17 of the director of the laboratory operating within the facility.

18 D. Persons in charge of a residential or day program, service, or facility licensed or operated by
19 any agency of the Commonwealth, or a school, child care center, or summer camp. Any person
20 in charge of a residential or day program, service, or facility licensed or operated by any agency
21 of the Commonwealth, or a school, child care center, or summer camp as defined in § 35.1-1 of
22 the Code of Virginia shall report immediately to the local health department the presence or
23 suspected presence in his program, service, facility, school, child care center, or summer camp
24 of persons who have common symptoms suggesting an outbreak situation. Such persons may
25 report additional information, including ~~individual cases of~~ identifying and contact information for
26 individuals with communicable diseases of public health concern or individuals who are involved

1 in outbreaks that occur in their facilities, as necessary to facilitate public health investigation and
2 disease control. Any person so reporting shall be immune from liability as provided by § 32.1-38
3 of the Code of Virginia.

4 E. Local health directors. The local health director shall forward any report of a disease or report
5 of evidence of a disease which has been made on a resident of his jurisdiction to the Office of
6 Epidemiology within three days of receipt. This report shall be submitted immediately by the
7 most rapid means available if the disease is one requiring rapid communication, as required in
8 12VAC5-90-80 C. All such rapid reporting shall be confirmed in writing and submitted to the
9 Office of Epidemiology, by either a paper report or entry into a shared secure electronic disease
10 surveillance system, within three days. Furthermore, the local health director shall immediately
11 forward to the appropriate local health director any disease reports on individuals residing in the
12 latter's jurisdiction or to the Office of Epidemiology on individuals residing outside Virginia. The
13 Office of Epidemiology shall be responsible for notifying other state health departments of
14 reported illnesses in their residents and [ef for] notifying CDC as necessary and appropriate.

15 F. Persons in charge of hospitals, nursing facilities or nursing homes, assisted living facilities,
16 and correctional facilities. In accordance with § 32.1-37.1 of the Code of Virginia, any person in
17 charge of a hospital, nursing facility or nursing home, assisted living facility, or correctional
18 facility shall, at the time of transferring custody of any dead body to any person practicing
19 funeral services, notify the person practicing funeral services or his agent if the dead person
20 was known to have had, immediately prior to death, an infectious disease which may be
21 transmitted through exposure to any bodily fluids. These include any of the following infectious
22 diseases:

- 23 Creutzfeldt-Jakob disease
- 24 Human immunodeficiency virus infection
- 25 Hepatitis B
- 26 Hepatitis C

1 Monkeypox

2 Rabies

3 Smallpox

4 Syphilis, infectious

5 Tuberculosis, active disease

6 Vaccinia, disease or adverse event

7 Viral hemorrhagic fever

8 G. Employees, [~~applicants~~ conditional employees], and persons in charge of food

9 establishments. 12VAC5-421-80 of the Food Regulations requires a food employee or ~~applicant~~

10 conditional employee to notify the person in charge of the food establishment when diagnosed

11 with certain diseases that are transmissible through food. ~~12VAC5-421-120~~ and requires the

12 person in charge of the food establishment to notify the ~~health department~~ regulatory authority.

13 Refer to the ~~appropriate sections~~ 12VAC5-421-80 of the Virginia Administrative Code for further

14 guidance and clarification regarding these reporting requirements.

15 12VAC5-90-100

16 Part IV

17 Control of Disease

18 12VAC5-90-100. Methods.

19 The board and commissioner shall use appropriate disease control measures to manage the

20 diseases listed in 12VAC5-90-80 A, including but not limited to those described in the "Methods

21 of Control" sections of the ~~18th~~ 20th Edition of the Control of Communicable Diseases Manual

22 (~~2004~~) (2015) published by the American Public Health Association. The board and

23 commissioner reserve the right to use any legal means to control any disease which is a threat

24 to the public health.

25 When notified about a disease specified in 12VAC5-90-80, the local health director or his

26 designee shall have the authority and responsibility to perform contact tracing/contact services

1 for HIV infection, infectious syphilis, and active tuberculosis disease and may perform contact
2 services for the other diseases if deemed necessary to protect the public health. All contacts of
3 HIV infection shall be afforded the opportunity for appropriate counseling, testing, and individual
4 face-to-face disclosure of their test results. In no case shall names of informants or infected
5 individuals be revealed to contacts by the health department. All information obtained shall be
6 kept strictly confidential.

7 The local health director or his designee shall review reports of diseases received from his
8 jurisdiction and follow up such reports, when indicated, with an appropriate investigation in order
9 to evaluate the severity of the problem. The local health director or his designee may
10 recommend to any individual or group of individuals appropriate public health control measures,
11 including but not limited to quarantine, isolation, immunization, decontamination, or treatment.
12 He shall determine in consultation with the Office of Epidemiology and the commissioner if
13 further investigation is required and if one or more forms of quarantine ~~and/or~~, isolation, or both
14 will be necessary.

15 Complete isolation shall apply to situations where an individual is infected with a communicable
16 disease of public health significance (including but not limited to active tuberculosis disease or
17 HIV infection) and is engaging in behavior that places others at risk for infection with the
18 communicable disease of public health significance, in accordance with the provisions of Article
19 3.01 (~~§ 32.1-48.02~~ 32.1-48.01 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

20 Modified isolation shall apply to situations in which the local health director determines that
21 modifications of activity are necessary to prevent disease transmission. Such situations shall
22 include but are not limited to the temporary exclusion of a child with a communicable disease
23 from school, the temporary exclusion of an individual with a communicable disease from food
24 handling or patient care, the temporary prohibition or restriction of an individual with a
25 communicable disease from using public transportation, the requirement that a person with a

1 communicable disease use certain personal protective equipment, or restrictions of other
2 activities that may pose a risk to the health of others.
3 Protective isolation shall apply to situations such as the exclusion, under § 32.1-47 of the Code
4 of Virginia, of any unimmunized child from a school in which an outbreak, potential epidemic, or
5 epidemic of a vaccine preventable disease has been identified.
6 To the extent permitted by the Code of Virginia, the local health director may be authorized as
7 the commissioner's designee to implement the forms of isolation described in this section. When
8 these forms of isolation are deemed to be insufficient, the local health director may use the
9 provisions of Article 3.01 (§ 32.1-48.01 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia
10 for the control of communicable diseases of public health significance or, in consultation with the
11 Office of Epidemiology, shall provide sufficient information to enable the commissioner to
12 prepare an order or orders of isolation ~~and/or~~, quarantine, or both under Article 3.02 (§ 32.1-
13 48.05 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia for the control of communicable
14 diseases of public health threat.

15 12VAC5-90-110

16 Part V

17 Immunization of Persons Less Than 18 Years of Age

18 12VAC5-90-110. Dosage and age requirements for immunizations; obtaining immunizations.

19 A. Every person in Virginia less than 18 years of age shall be immunized in accordance with the
20 most recent Immunization Schedule developed and published by the ~~Centers for Disease~~
21 ~~Control and Prevention (CDC)~~ CDC, Advisory Committee on Immunization Practices (ACIP), the
22 American Academy of Pediatrics (AAP), and the American Academy of Family Physicians
23 (AAFP). Requirements for school and day care attendance are addressed in 12VAC5-110.
24 B. The required immunizations may be obtained from a physician ~~licensed to practice medicine~~
25 ~~or from the local health department,~~ registered nurse, or other licensed professional [as]

1 authorized by the Code of Virginia [to administer immunizations at locations to include private
2 settings or local health departments].

3 12VAC5-90-280

4 Part XII

5 Reporting of Dangerous Microbes and Pathogens

6 12VAC5-90-280. ~~Definitions.~~ Reporting of dangerous microbes and pathogens.

7 A. Definitions. The following words and terms when used in this part shall have the following
8 meanings unless the context clearly indicates otherwise:

9 "Biologic agent" means any microorganism (including, but not limited to, bacteria, viruses, fungi,
10 rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or
11 synthesized component of any such microorganism or infectious substance, capable of causing
12 death, disease, or other biological malfunction in a human, an animal, a plant, or other living
13 organism; deterioration of food, water, equipment, supplies, or material of any kind; or
14 deleterious alteration of the environment.

15 "CDC" means the Centers for Disease Control and Prevention of the U.S. Department of Health
16 and Human Services.

17 "Diagnosis" means the analysis of specimens for the purpose of identifying or confirming the
18 presence or characteristics of a select agent or toxin, provided that such analysis is directly
19 related to protecting the public health or safety.

20 "Proficiency testing" means a sponsored, time-limited analytical trial whereby one or more
21 analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for
22 analysis and where final results are graded, scores are recorded and provided to participants,
23 and scores for participants are evaluated.

24 "Responsible official" means any person in charge of directing or supervising a laboratory
25 conducting business in the Commonwealth of Virginia. At colleges and universities, the
26 responsible official shall be the president of the college or university or his designee. At private,

1 state, or federal organizations, the responsible official shall be the laboratory director or a chief
2 officer of the organization or his designee.

3 "Select agent or toxin" or "select agent and toxin" means all those biological agents or toxins as
4 defined by federal regulations in 42 CFR Part 73, including: ~~1. Health and Human Services~~
5 ~~(HHS) select agents and toxins, as outlined in 42 CFR 73.4~~ and overlap select agents and
6 toxins.

7 ~~2. HHS overlap select agents and toxins, as outlined in 42 CFR 73.5.~~

8 "Toxin" means the toxic material or product of plants, animals, microorganisms (including but
9 not limited to bacteria, viruses, fungi, rickettsiae, or protozoa); or infectious substances; or a
10 recombinant or synthesized molecule, whatever the origin and method of production; and
11 includes any poisonous substance or biological product that may be engineered as a result of
12 biotechnology or produced by a living organism; or any poisonous isomer or biological product,
13 homolog, or derivative of such a substance.

14 "Verification" means the process required to assure the accuracy, precision, and the analytical
15 sensitivity and specificity of any procedure used for diagnosis.

16 B. Administration. The dangerous microbes and pathogens will be known as "select agents and
17 toxins." The select agent and toxin registry will be maintained by the Virginia Department of
18 Health, Office of Epidemiology, Division of Surveillance and Investigation.

19 C. Reportable agents. The board declares the select agents and toxins and overlap select
20 agents and toxins outlined in 42 CFR Part 73 to be reportable and adopts it herein by reference
21 including subsequent amendments and editions. The select agents and toxins are to be
22 reportable by the persons enumerated in subsection F of this section.

23 D. Items to report. Each report shall be made on a form determined by the department and shall
24 contain the following: name, source and characterization information on select agents and
25 toxins and quantities held; objectives of the work with the agent; location (including building and
26 room) where each select agent or toxin is stored or used; identification information of persons

1 with access to each agent; identification information of the person in charge of each of the
2 agents; and the name, position and identification information of one responsible official as a
3 single point of contact for the organization. The report shall also indicate whether the laboratory
4 is registered with the CDC Select Agent Program and may contain additional information as
5 required by 42 CFR Part 73 or the department.

6 E. Timing of reports. Reports shall be made to the department within seven calendar days of
7 submission of an application to the CDC Select Agent Program. By January 31 of every year,
8 laboratories shall provide a written update to the department, which shall include a copy of the
9 federal registration certificate received through the CDC Select Agent Program.

10 In the event that a select agent or toxin that has previously been reported to the department is
11 destroyed, a copy of federal forms addressing the destruction of the select agent or toxin must
12 be submitted to the department within seven calendar days of submission to the CDC Select
13 Agent Program.

14 In the event that a select agent or toxin, or a specimen or isolate from a specimen containing a
15 select agent or toxin, has previously been reported to the department and is subsequently
16 transferred to a facility eligible for receiving the items, a copy of federal forms addressing the
17 transfer of the select agent or toxin must be submitted to the department within seven calendar
18 days of submission to the CDC Select Agent Program.

19 In the event of a suspected release, loss, or theft of any select agent or toxin, the responsible
20 official at a laboratory shall make a report to the department immediately by the most rapid
21 means available, preferably by telephone. The rapid report shall be followed up by a written
22 report within seven calendar days and shall include the following information:

23 1. The name of the biologic agent and any identifying information (e.g., strain or other
24 characterization information);

25 2. An estimate of the quantity released, lost, or stolen;

26 3. An estimate of the time during which the release, loss, or theft occurred; and

1 4. The location (building, room) from or in which the release, loss, or theft occurred. The report
2 may contain additional information as required by 42 CFR Part 73 or the department.
3 The department must be notified in writing of any change to information previously submitted to
4 the department. If a new application or an amendment to an existing application is filed with the
5 CDC Select Agent Program, a copy of the application or amendment must be submitted to the
6 department within seven calendar days of submission to the CDC Select Agent Program.

7 F. Those required to report. The ~~[responsible official in charge of a laboratory conducting~~
8 ~~business in the Commonwealth~~ laboratory director] shall be responsible for annual reporting of
9 select agents and toxins to the Virginia Department of Health and for the reporting of any
10 changes within the time periods as specified within these regulations. Such reports shall be
11 made on forms to be determined by the department. Any person making such reports as
12 authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of
13 Virginia.

14 G. Exemption from reporting. A person who detects a select agent or toxin for the purpose of
15 diagnosing a disease, verification, or proficiency testing and either transfers the specimens or
16 isolates containing the select agent or toxin to a facility eligible for receiving them or destroys
17 them on site is not required to make a report except as required by 12VAC5-90-80 and
18 12VAC5-90-90. Proper destruction of the agent must take place through autoclaving,
19 incineration, or by a sterilization or neutralization process sufficient to cause inactivation. The
20 transfer or destruction must occur within seven calendar days after identification of a select
21 agent or toxin used for diagnosis or testing and within 90 calendar days after receipt for
22 proficiency testing.

23 Any additional exemptions from reporting under 42 CFR Part 73, including subsequent
24 amendments and editions, are also exempt from reporting under this regulation; however, the
25 department must be notified of the exemption by submitting a copy of federal forms addressing
26 the exemption within seven calendar days of submission to the CDC Select Agent Program.

1 H. Release of reported information. Reports submitted to the select agent and toxin registry
2 shall be confidential and shall not be a public record pursuant to the Freedom of Information
3 Act, regardless of submitter. Release of information on select agents or toxins shall be made
4 only by order of the State Health Commissioner to the CDC and state and federal law-
5 enforcement agencies in any investigation involving the release, theft, or loss of a select agent
6 or toxin required to be reported to the department under this regulation.

7 12VAC5-90-290

8 12VAC5-90-290. Authority. (Repealed.)

9 Chapter 2 (~~§ 32.1-35 et seq.~~) of Title 32.1 of the Code of Virginia authorizes the reporting of
10 dangerous microbes and pathogens to the department. Specifically, ~~§ 32.1-35~~ directs the board
11 to promulgate regulations specifying which dangerous microbes and pathogens are to be
12 reportable and the method and timeframe by which they are to be reported by laboratories.

13 12VAC5-90-300

14 12VAC5-90-300. Administration. (Repealed.)

15 The dangerous microbes and pathogens will be known as "select agents and toxins." The select
16 agent and toxin registry will be maintained by the Virginia Department of Health, Office of
17 Epidemiology, Division of Surveillance and Investigation.

18 12VAC5-90-310

19 12VAC5-90-310. Reportable agents. (Repealed.)

20 The board declares the select agents and toxins outlined in 42 CFR 73.4 and 42 CFR 73.5 to be
21 reportable, and adopts it herein by reference including subsequent amendments and editions.

22 The select agents and toxins are to be reportable by the persons enumerated in 12VAC5-90-
23 340.

24 12VAC5-90-320

25 12VAC5-90-320. Items to report. (Repealed.)

1 Each report shall be made on a form determined by the department and shall contain the
2 following: name, source and characterization information on select agents and toxins and
3 quantities held; objectives of the work with the agent; location (including building and room)
4 where each select agent or toxin is stored or used; identification information of persons with
5 access to each agent; identification information of the person in charge of each of the agents;
6 and the name, position and identification information of one responsible official as a single point
7 of contact for the organization. The report shall also indicate whether the laboratory is registered
8 with the CDC Select Agent Program and may contain additional information as required by 42
9 CFR Part 73 or the department.

10 12VAC5-90-330

11 12VAC5-90-330. Timing of reports. (Repealed.)

12 Initial reports shall be made by October 26, 2004. Thereafter, reports shall be made to the
13 department within seven calendar days of submission of an application to the CDC Select Agent
14 Program. By January 31 of every year, laboratories shall provide a written update to the
15 department, which shall include a copy of the federal registration certificate received through the
16 CDC Select Agent Program.

17 In the event that a select agent or toxin that has previously been reported to the department is
18 destroyed, a copy of federal forms addressing the destruction of the select agent or toxin must
19 be submitted to the department within seven calendar days of submission to the CDC Select
20 Agent Program.

21 In the event that a select agent or toxin, or a specimen or isolate from a specimen containing a
22 select agent or toxin, has previously been reported to the department and is subsequently
23 transferred to a facility eligible for receiving the items, a copy of federal forms addressing the
24 transfer of the select agent or toxin must be submitted to the department within seven calendar
25 days of submission to the CDC Select Agent Program.

1 In the event of a suspected release, loss or theft of any select agent or toxin, the responsible
2 official at a laboratory shall make a report to the department within 24 hours by the most rapid
3 means available, preferably that of telecommunication (e.g., telephone, telephone transmitted
4 facsimile, pagers, etc.) The rapid report shall be followed up by a written report within seven
5 calendar days and shall include the following information:

- 6 1. The name of the biologic agent and any identifying information (e.g., strain or other
7 characterization information);
- 8 2. An estimate of the quantity released, lost or stolen;
- 9 3. An estimate of the time during which the release, loss or theft occurred; and
- 10 4. The location (building, room) from or in which the release, loss or theft occurred. The report
11 may contain additional information as required by 42 CFR Part 73 or the department.

12 The department must be notified in writing of any changes to information previously submitted to
13 the department. If a new application or an amendment to an existing application is filed with the
14 CDC Select Agent Program, a copy of the application or amendment must be submitted to the
15 department within seven calendar days of submission to the CDC Select Agent Program.

16 12VAC5-90-340

17 12VAC5-90-340. ~~Those required to report. (Repealed.)~~

18 The responsible official in charge of a laboratory conducting business in the Commonwealth
19 shall be responsible for annual reporting of select agents and toxins to the Virginia Department
20 of Health and for the reporting of any changes within the time periods as specified within these
21 regulations. Such reports shall be made on forms to be determined by the department. Any
22 person making such reports as authorized herein shall be immune from liability as provided by §
23 32.1-38 of the Code of Virginia.

24 12VAC5-90-350

25 12VAC5-90-350. ~~Exemption from reporting. (Repealed.)~~

1 ~~A person who detects a select agent or toxin for the purpose of diagnosing a disease,~~
2 ~~verification, or proficiency testing and either transfers the specimens or isolates containing the~~
3 ~~select agent or toxin to a facility eligible for receiving them or destroys them onsite is not~~
4 ~~required to make a report. Proper destruction of the agent must take place through autoclaving,~~
5 ~~incineration, or by a sterilization or neutralization process sufficient to cause inactivation. The~~
6 ~~transfer or destruction must occur within seven calendar days after identification of a select~~
7 ~~agent or toxin used for diagnosis or testing and within 90 calendar days after receipt for~~
8 ~~proficiency testing.~~

9 ~~Any additional exemptions from reporting under 42 CFR 73.6, including subsequent~~
10 ~~amendments and editions, are also exempt from reporting under this regulation; however, the~~
11 ~~department must be notified of the exemption by submitting a copy of federal forms addressing~~
12 ~~the exemption within seven calendar days of submission to the CDC Select Agent Program.~~

13 ~~12VAC5-90-360~~

14 ~~12VAC5-90-360. Release of reported information. (Repealed.)~~

15 ~~Reports submitted to the select agent and toxin registry shall be confidential and shall not be a~~
16 ~~public record pursuant to the Freedom of Information Act. Release of information on select~~
17 ~~agents or toxins shall be made only by order of the State Health Commissioner to the CDC and~~
18 ~~state and federal law enforcement agencies in any investigation involving the release, theft, or~~
19 ~~loss of a select agent or toxin required to be reported to the department under this regulation.~~

20 ~~12VAC5-90-9998~~

21 ~~FORMS (12VAC5-90)~~

22 ~~Virginia Department of Health Confidential Morbidity Report, Epi-1 (rev. 3/07)~~

23 ~~Confidential Morbidity Report, Epi-1 (rev. 10/11)~~

24 ~~Virginia Cancer Registry Reporting Form (rev. 1/98)~~

25 ~~12VAC5-90-9999~~

26 ~~DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-90)~~

- 1 ~~Control of Communicable Diseases Manual, 18th Edition, American Public Health Association,~~
- 2 ~~2004.~~
- 3 Control of Communicable Diseases Manual, 20th Edition, American Public Health Association,
- 4 2015
- 5

MAIL THE TOP TWO COPIES TO YOUR LOCAL HEALTH DEPARTMENT

VIRGINIA DEPARTMENT OF HEALTH
Confidential Morbidity Report

Patient's Name (Last, First, Middle Initial):	SSN: _____
Patient's Address (Street, City or Town, State, Zip Code):	Home #: () _____
	Work #: () _____
City or County of Residence	

Date of Birth: (mm/dd/yyyy)	Age:	Race: <input type="checkbox"/> American Indian/Alaskan Native <input type="checkbox"/> Asian <input type="checkbox"/> Black/African American <input type="checkbox"/> Hawaiian/Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown	Hispanic: <input type="checkbox"/> Yes <input type="checkbox"/> No	Sex: <input type="checkbox"/> F <input type="checkbox"/> M
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DISEASE OR CONDITION:	Pregnant: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Death: <input type="checkbox"/> Yes <input type="checkbox"/> No Death Date:
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Date of Onset:	Date of Diagnosis:	Influenza: (Report # and type only. No patient identification) Number of Cases: _____ Type, if Known: _____
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Physician's Name:	Phone #: () _____
Address:	

Hospital Admission: <input type="checkbox"/> Yes <input type="checkbox"/> No	Hospital Name:
Date of Admission:	Medical Record Number:

Laboratory Information and Results

Source of Specimen:	Date Collected:
---------------------	-----------------

Laboratory Test(s) and Finding(s):

Name/Address of Lab:
CLIA Number:

Other Information

Comments: (e.g., Risk situation [food handling, patient care, day care], Treatment [including dates], Immunization status [including dates], Signs/Symptoms, Exposure, Outbreak-associated, etc.)

Name, Address, and Phone Number of Person Completing this Form:	Date Reported:
Check here if you need more of these forms, or call your local health department. <input type="checkbox"/> (Be sure your address is complete.)	

For Health Department Use

Date Received:
VEDSS Patient ID:

Please complete as much of this form as possible

Form Epi-1, 10/2011