

**State Board of Health
Nominating Committee
Agenda
June 1, 2017 – 8:30 a.m.
Perimeter Center – Hearing Room 5**

Welcome and Introductions	Tommy East, Chair
Discussion	Nominating Committee Members
Adjourn	

**State of Board of Health
Agenda
June 1, 2017 – 9:00 a.m.
Perimeter Center – Boardroom 2**

Call to Order and Welcome	Bruce Edwards, Chair
Pledge of Allegiance	Faye Prichard
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of March 16, 2017 Minutes	Mr. Edwards
Commissioner's Report	Marissa Levine, MD, MPH, FAAFP State Health Commissioner
Affordable Care Act/American Health Care Act - Overview	Michael Fraser, PhD, CAE, Executive Director Association of State and Territorial Health Officials
Break	
Abortion Facility Licensure Status Report	Erik Bodin, Director Office of Licensure and Certification
Regulatory Action Update	Mr. Hilbert
Public Comment Period	
Preview of the Board of Health Annual Report - Virginia's Plan for Well-Being	Mr. Hilbert; Leslie Hogle, Ph.D, Director, Division of Population Health Data

Regulatory Action Items

Regulations for the Licensure of
Nursing Facilities
12VAC5-371
(Fast Track Amendments)

Mr. Bodin

Working Lunch/Regulatory Action Items

State Medical Facilities Plan
12VAC5-230
(Proposed Amendments)

Mr. Bodin

Regulations for the Immunization
of School Children
12VAC5-110
(Fast Track Amendments)

Dr. Laurie Forlano, Director
Office of Epidemiology

Report of Nominating Committee

Mr. East

Election of Officers and Executive
Committee Members

Mr. Edwards

Member Reports

Other Business

Adjourn



COMMONWEALTH of VIRGINIA

Department of Health

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

P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: May 10, 2017

TO: Virginia State Board of Health

FROM: Erik Bodin, Director, Office of Licensure and Certification

SUBJECT: Regulations for the Licensure of Nursing Facilities (12VAC5-371) – Electronic Monitoring

Enclosed for your review are fast track amendments to the Regulations for the Licensure of Nursing Facilities (12VAC5-371).

Senate Bill 553 enacted by the 2016 General Assembly mandates this regulatory action. SB553 requires the Board of Health to promulgate regulations that at a minimum address the audio-visual recording of residents in nursing facilities. SB553 requires that such regulations shall include provisions related to (i) resident privacy, (ii) notice and disclosure, (iii) liability, (iv) ownership and maintenance of equipment, (v) cost, (vi) recording and data security, and (vii) nursing facility options for both nursing facility-managed recording and resident-managed recording. SB553 required the convening of a workgroup that included representatives of nursing facilities, advocates for residents of nursing facilities, and other stakeholders to make recommendations to the Board on such regulations. The workgroup built on the regulatory language that had previously come before the Board and the language of the 2004 Virginia Department of Health (VDH) Guidance Document. For that reason, the Board is requested to approve the utilization of the fast track process authorized by the Administrative Process Act. The amendments contain provisions pertaining to definitions, a framework to address policies and procedures, informed consent, admission, discharge or transfer, the equipment request process, notice procedures, retention and ownership of tapes or recordings, and reporting suspected abuse, neglect, accident or injury discovered through electronic monitoring.

In drafting the amendments VDH convened a workgroup pursuant to SB553. The workgroup met several times and workgroup members provided recommendations regarding regulatory language. VDH reviewed the recommendations of the workgroup and, from that information, VDH drafted the amending language which is presented to the Board.

The Board of Health is requested to approve the fast track amendments. Should the Board of Health approve the amendments, they 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 amendments will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. The amendments will become effective 45-days following publication in the Virginia Register of Regulations.



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	May 10, 2017

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.

Senate Bill 553 enacted by the 2016 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. SB553 (2016) 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 proposed amendments in this fast track action are a combination of the 2004 guidelines which were developed to assist facilities with the privacy issues that may arise when installing electronic monitoring equipment and the work of a workgroup assembled pursuant to SB553. Installing such equipment is not mandatory on the nursing home; 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, and discharge or transfer. The proposed amendments include 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.

Enter statement here

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.

Senate Bill 553 enacted by the 2016 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. SB553 (2016) required that the Board convene a workgroup that includes representatives of nursing facilities, advocates for residents of nursing facilities, and other stakeholders to make recommendations to the Board concerning such 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.

Senate Bill 553 enacted by the 2016 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. 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, and discharge or transfer. The proposed amendments include 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 proposed amendments 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?

SB553 (2016) mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. The proposed amendments were developed cooperatively with the assistance of a workgroup convened pursuant to SB553 and relied heavily on language included in a VDH Guidance Document in use since 2004. Therefore, VDH believes the proposed amendments 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 quality of care and safety for nursing home residents 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.

SB553 (2016) mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. 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 SB553 (2016).

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>
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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.	The 281 licensed nursing facilities within the Commonwealth of Virginia, patients or residents of those facilities and their family members or legal representatives.
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.	All 281 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.
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.	None, there are no costs unless the facility receives a request to install equipment. The proposed amendments provide that such costs can be charged to the family, patient or resident seeking implementation of the electronic monitoring. There will be a cost for those individuals (patients, residents, family members) who wish to avail themselves of electronic monitoring.
Beneficial impact the regulation is designed to produce.	Provides the controls necessary to assure that resident autonomy and rights to personal privacy are not violated.

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.

SB553 (2016) mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. 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 SB553 (2016).

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.

Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response

Not applicable.

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 proposed amendments 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 follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-371-10		Definitions. Current definitions all remain unchanged.	<p>Defined terms to be added: <u>“Electronic monitoring” means an unmanned video recording system, with or without audio capability, installed in the room of a resident.</u> <u>“Facility-managed” is an electronic monitoring system that is installed, controlled, and maintained by the nursing facility in accordance with the facility’s policies.</u> <u>“Resident-managed” is an electronic monitoring system that is installed, controlled, and maintained by the resident with the knowledge of the nursing facility.</u></p> <p>Intent: Provides definition to terms and phrases used in 12VAC5-371-191.</p> <p>Likely impact: provides clarity to the new regulatory section.</p>
N/A	12VAC5-371-191- Electronic monitoring in resident rooms.	N/A	<p><u>A. All requests for electronic monitoring shall be made in writing and signed by the resident or the resident’s responsible party if the resident has been properly assessed incapable of requesting and authorizing the monitoring.</u></p> <p><u>B. Only electronic monitoring in accordance with this section is permitted.</u></p> <p><u>C. A facility shall not refuse to admit an individual and shall not discharge or transfer a 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 if the resident is incapable, the resident's responsible party. 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. Consent 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 managing the electronic monitoring program.</u></p> <p><u>G. Facilities may designate custodial ownership of any recordings from monitoring devices to the resident or the resident’s</u></p>

			<p><u>responsible party. Facility retained recordings shall be considered part of the resident's medical record and shall be retained for no less than two years or as required by state and federal laws.</u></p> <p><u>H. If a facility chooses to retain ownership of recordings, the facility shall not permit viewings of recordings without consent of the resident or the resident's responsible party except to the extent that disclosure is required by law through a court order or pursuant to a lawful subpoena duces tecum. Should a resident or a resident's responsible party approve viewing, the facility shall accommodate viewing of any recordings, including, but not limited to providing:</u></p> <ol style="list-style-type: none"> <u>1. Appropriate playing/viewing equipment;</u> <u>2. Privacy during viewing; and</u> <u>3. Viewing times convenient to the resident or the resident's responsible party.</u> <p><u>I. A facility shall require its staff to report any incidents regarding safety or quality of care discovered as a result of viewing a recording immediately to the facility administrator and to the OLC. Facilities shall instruct the resident or the resident's responsible party of this reporting requirement and shall provide the resident or the resident's responsible party with the OLC's Complaint Hotline telephone number.</u></p> <p><u>J. A facility shall have no obligation to seek access to a recording in its possession or to have knowledge of a recording's content, unless the facility is aware of a recorded incident of suspected abuse, neglect, accident or injury; or the resident or the resident's responsible party, or a government agency seeks to use a recording. 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 or the resident's responsible party to be responsible for all aspects of the operation of the monitoring equipment, including the removal and replacement of recordings, and for firewall protections to prevent images that would violate obscenity laws from being inadvertently shown on the Internet.</u></p> <p><u>L. A facility shall prohibit staff from refusing to enter a resident's room solely because of electronic monitoring.</u></p>
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		<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 responsible party 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, recording media 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 residents, or if the resident is incapable, the resident's responsible party, assigned to the monitored room shall be obtained prior to any electronic monitoring equipment being installed.</u></p> <p><u>R. A facility may require the resident or a resident's responsible party 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 include, 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</u></p>
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			<p><u>resident's room stating that an electronic monitoring device is in operation.</u></p> <p><u>V. Facilities shall notify all staff and their OLC Long Term Care Supervisor that electronic monitoring is in use.</u></p> <p><u>W. A facility shall prohibit staff from covert monitoring in violation of this chapter. Facilities shall instruct the resident or the resident's responsible party of this prohibition and shall provide the resident or the resident's responsible party with the OLC's Complaint Hotline telephone number.</u></p> <p><u>X. If covert monitoring is discovered, the facility may require a resident or a resident's responsible party to meet all the requirements for authorized monitoring prior to the continuation of monitoring.</u></p> <p><u>Y. Each nursing facility, including those that choose not to offer electronic monitoring, 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><u>Z. A facility shall prohibit staff from tampering with electronic monitoring in violation of this chapter. Facilities shall instruct the resident or the resident's responsible party of this prohibition and shall provide the resident or the resident's responsible party with the OLC's Complaint Hotline telephone number.</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 consent. These provisions largely already exist in a Guidance document published by VDH in 2004. The Department is simply placing those provisions, updated with input from the workgroup, into the regulations as required by SB553 (2016).</p> <p>Likely impact: Greater patient safety, more comprehensive regulations.</p>
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Project 4519 - none

DEPARTMENT OF HEALTH
CH371- Amend regulations related to electronic monitoring

1 **12VAC5-371-191. Electronic monitoring in resident rooms.**

2 12VAC5-371-10. Definitions

3 The following words and terms when used in this chapter shall have the following meanings
4 unless the context clearly indicates otherwise.

5 "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or
6 punishment with resulting physical harm, pain or mental anguish, or deprivation by an
7 individual, including caretaker, of goods or services that are necessary to attain or maintain
8 physical, mental, and psychosocial well-being. This includes verbal, sexual, physical or mental
9 abuse.

10 "Administrator" means the individual licensed by the Virginia Board of Long-Term Care
11 Administrators and who has the necessary authority and responsibility for management of the
12 nursing facility.

13 "Admission" means the process of acceptance into a nursing facility, including orientation, rules
14 and requirements, and assignment to appropriate staff. Admission does not include readmission
15 to the facility after a temporary absence.

16 "Advance directive" means (i) a witnessed written document, voluntarily executed by the
17 declarant in accordance with the requirements of § 54.1-2983 of the Code of Virginia, or (ii) a
18 witnessed oral statement, made by the declarant subsequent to the time he is diagnosed as
19 suffering from a terminal condition and in accordance with the provision of § 54.1-2983 of the
20 Code of Virginia.

21 "Assessment" means the process of evaluating a resident for the purpose of developing a profile
22 on which to base services. Assessment includes information gathering, both initially and on an
23 ongoing basis, designed to assist the multi-disciplinary staff in determining the resident's need
24 for care, and the collection and review of resident-specific data.

25 "Attending physician" means a physician currently licensed by the Virginia Board of Medicine
26 and identified by the resident, or legal representative, as having the primary responsibility in
27 determining the delivery of the resident's medical care.

28 "Board" means the Board of Health.

29 "Certified nurse aide" means the title that can only be used by individuals who have met the
30 requirements to be certified, as defined by the Virginia Board of Nursing, and who are listed in
31 the nurse aide registry.

32 "Chemical restraint" means a psychopharmacologic drug (a drug prescribed to control mood,
33 mental status, or behavior) that is used for discipline or convenience and not required to treat
34 medical symptoms or symptoms from mental illness or mental retardation that prohibit an
35 individual from reaching his highest level of functioning.

36 "Clinical record" means the documentation of health care services, whether physical or mental,
37 rendered by direct or indirect resident-provider interactions. An account compiled by physicians
38 and other health care professionals of a variety of resident health information, such as
39 assessments and care details, including testing results, medicines, and progress notes.

40 "Commissioner" means the State Health Commissioner.

41 "Complaint" means any allegation received by the Department of Health other than an incident
42 reported by the facility staff. Such allegations include, but are not limited to, abuse, neglect,
43 exploitation, or violation of state or federal laws or regulations.

44 "Comprehensive plan of care" means a written action plan, based on assessment data that
45 identifies a resident's clinical and psychosocial needs, the interventions to meet those needs,
46 treatment goals that are measurable and that documents the resident's progress toward meeting
47 the stated goals.

48 "Construction" means the building of a new nursing facility or the expansion, remodeling, or
49 alteration of an existing nursing facility and includes the initial and subsequent equipping of the
50 facility.

51 "Department" means the Virginia Department of Health.

52 "Dignity" means staff, in their interactions with residents, carry out activities which assist a
53 resident in maintaining and enhancing the resident's self-esteem and self-worth.

54 "Discharge" means the process by which the resident's services, delivered by the nursing facility,
55 are terminated.

56 "Discharge summary" means the final written summary of the services delivered, goals achieved
57 and post-discharge plan or final disposition at the time of discharge from the nursing facility. The
58 discharge summary becomes a part of the clinical record.

59 "Drug" means (i) articles or substances recognized in the official United States "Drug"
60 Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United
61 States, or any supplement to any of them; (ii) articles or substances intended for the use in the
62 diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal; (iii)
63 articles or substances, other than food, intended to affect the structure or any function of the body
64 of man or other animal; and (iv) articles or substances intended for use as a component of any
65 article specified in clause (i), (ii), or (iii). This does not include devices or their components,
66 parts or accessories.

67 "Electronic monitoring" means an unmanned video recording system, with or without audio
68 capability, installed in the room of a resident.

69 "Emergency preparedness plan" means a component of a nursing facility's safety management
70 program designed to manage the consequences of natural disasters or other emergencies that
71 disrupt the nursing facility's ability to provide care.

72 "Employee" means a person who performs a specific job function for financial remuneration on a
73 full-time or part-time basis.

74 "Facility-managed" is an electronic monitoring system that is installed, controlled, and
75 maintained by the nursing facility in accordance with the facility's policies.

76 "Full-time" means a minimum of 35 hours or more worked per week in the nursing facility.

77 "Guardian" means a person legally invested with the authority and charged with the duty of
78 taking care of the resident, managing his property and protecting the rights of the resident who
79 has been declared by the circuit court to be incapacitated and incapable of administering his own
80 affairs. The powers and duties of the guardian are defined by the court and are limited to matters
81 within the areas where the resident in need of a guardian has been determined to be
82 incapacitated.

83 "Medication" means any substance, whether prescription or over-the-counter drug, that is taken
84 orally or injected, inserted, topically applied, or otherwise administered.

85 "Neglect" means a failure to provide timely and consistent services, treatment or care to a
86 resident or residents that are necessary to obtain or maintain the resident or residents' health,
87 safety or comfort; or a failure to provide timely and consistent goods and services necessary to
88 avoid physical harm, mental anguish, or mental illness.

89 "Nursing facility" means any nursing home as defined in § 32.1-123 of the Code of Virginia.

90 "OLC" means the Office of Licensure and Certification of the Virginia Department of Health.
91 "Person" means any individual, corporation, partnership, association, trust, or other legal entity,
92 whether governmental or private, owning, managing, or operating a nursing facility.
93 "Physical restraint" means any manual method or physical or mechanical device, material, or
94 equipment attached or adjacent to the resident's body that the individual cannot remove easily
95 which restricts freedom of movement or normal access to one's own body.
96 "Policy" means a written statement that describes the principles and guides and governs the
97 activities, procedures and operations of the nursing facility.
98 "Procedures" means a series of activities designed to implement program goals or policy, which
99 may or may not be written, depending upon the specific requirements within this chapter. For
100 inspection purposes, there must be evidence that procedures are actually implemented.
101 "Progress note" means a written statement, signed and dated by the person delivering the care,
102 consisting of a pertinent, chronological report of the resident's care. A progress note is a
103 component of the clinical record.
104 "Qualified" means meeting current legal requirements of licensure, registration or certification in
105 Virginia; having appropriate training and experience commensurate with assigned
106 responsibilities; or, if referring to a professional, possessing an appropriate degree or having
107 documented equivalent education, training or experience.
108 "Quality assurance" means systematic activities performed to determine the extent to which
109 clinical practice meets specified standards and values with regard to such things as
110 appropriateness of service assignment and duration, appropriateness of facilities and resources
111 utilized, adequacy and clinical soundness of care given. Such activities should also assure
112 changes in practice that do not meet accepted standards. Examples of quality assurance activities
113 include the establishment of facility-wide goals for resident care, the assessment of the
114 procedures used to achieve the goals, and the proposal of solutions to problems in attaining those
115 goals.
116 "Readmission" means a planned return to the nursing facility following a temporary absence for
117 hospitalization, off-site visit or therapeutic leave, or a return stay or confinement following a
118 formal discharge terminating a previous admission.
119 "Resident" means the primary service recipient, admitted to the nursing facility, whether that
120 person is referred to as a client, consumer, patient, or other term.

121 “Resident-managed” is an electronic monitoring system that is installed, controlled, and
122 maintained by the resident with the knowledge of the nursing facility.
123 "Responsible person or party" means an individual authorized by the resident to act for him as an
124 official delegate or agent. The responsible person may be a guardian, payee, family member or
125 any other individual who has arranged for the care of the resident and assumed this
126 responsibility. The responsible person or party may or may not be related to the resident. A
127 responsible person or party is not a guardian unless so appointed by the court.
128 "Supervision" means the ongoing process of monitoring the skills, competencies and
129 performance of the individual supervised and providing regular, face-to-face guidance and
130 instruction.
131 "Volunteer" means a person who, without financial remuneration, provides services to the
132 nursing facility.

133 **12VAC5-371-191. Electronic monitoring in resident rooms.**

134 A. All requests for electronic monitoring shall be made in writing and signed by the resident
135 or the resident’s responsible party if the resident has been properly assessed incapable of
136 requesting and authorizing the monitoring.

137 B. Only electronic monitoring in accordance with this section is permitted.

138 C. A facility shall not refuse to admit an individual and shall not discharge or transfer a
139 resident due to a request to conduct authorized electronic monitoring.

140 D. Family members cannot obtain electronic monitoring over the objections of the resident or
141 the resident's roommate. No equipment may be installed pursuant to 12VAC5-371-191 (Q) over
142 the objections of the resident, or if the resident is incapable, the resident’s responsible party.
143 Facilities shall not use monitoring equipment in violation of the law based solely on a family
144 member's request or approval.

145 E. Consent for electronic monitoring shall be kept in the resident's medical record.

146 F. Facilities shall designate one staff person to be responsible for managing the electronic
147 monitoring program.

148 G. Facilities may designate custodial ownership of any recordings from monitoring devices
149 to the resident or the resident’s responsible party. Facility retained recordings shall be considered

150 part of the resident's medical record and shall be retained for no less than two years or as
151 required by state and federal laws.

152 H. If a facility chooses to retain ownership of recordings, the facility shall not permit
153 viewings of recordings without consent of the resident or the resident's responsible party except
154 to the extent that disclosure is required by law through a court order or pursuant to a lawful
155 subpoena duces tecum. Should a resident or a resident's responsible party approve viewing, the
156 facility shall accommodate viewing of any recordings, including, but not limited to providing:

157 1. Appropriate playing/viewing equipment;

158 2. Privacy during viewing; and

159 3. Viewing times convenient to the resident or the resident's responsible party.

160 I. A facility shall require its staff to report any incidents regarding safety or quality of care
161 discovered as a result of viewing a recording immediately to the facility administrator and to the
162 OLC. Facilities shall instruct the resident or the resident's responsible party of this reporting
163 requirement and shall provide the resident or the resident's responsible party with the OLC's
164 Complaint Hotline telephone number.

165 J. A facility shall have no obligation to seek access to a recording in its possession or to have
166 knowledge of a recording's content, unless the facility is aware of a recorded incident of
167 suspected abuse, neglect, accident or injury; or the resident or the resident's responsible party, or
168 a government agency seeks to use a recording. Facilities shall immediately report suspected
169 abuse and neglect discovered as a result of using monitoring devices, as required by law.

170 K. A facility may require the resident or the resident's responsible party to be responsible for
171 all aspects of the operation of the monitoring equipment, including the removal and replacement
172 of recordings, and for firewall protections to prevent images that would violate obscenity laws
173 from being inadvertently shown on the Internet.

174 L. A facility shall prohibit staff from refusing to enter a resident's room solely because of
175 electronic monitoring.

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

178 N. A facility shall make reasonable physical accommodation for monitoring equipment
179 including:

180 1. Providing a reasonably secure place to mount the device; and

181 2. Providing access to power sources for the device.

182 O. A facility may require a resident or a resident's responsible party to pay for all costs, other
183 than the cost of electricity, associated with installing electronic monitoring equipment. Such
184 costs shall be reasonable and may include, but are not limited to: equipment, recording media
185 and installation, compliance with life safety and building/electrical codes, maintenance or
186 removal of the equipment, posting and removal of any public notices, or structural repairs to the
187 building resulting from the removal of the equipment. Facilities shall give 45 days notice of an
188 increase in monthly monitoring fees.

189 P. Any equipment installed for the purpose of monitoring a resident room shall be fixed and
190 unable to rotate.

191 Q. The informed consent of all residents, or if the resident is incapable, the resident's
192 responsible party, assigned to the monitored room shall be obtained prior to any electronic
193 monitoring equipment being installed.

194 R. A facility may require the resident or a resident's responsible party obtain the necessary
195 signed consent of other residents in the room.

196 S. A copy of any signed consent form shall be kept in the resident's medical record as well as
197 on file with the facility's designated electronic monitoring coordinator.

198 T. Any resident of a monitored room may condition his or her consent for use of monitoring
199 devices. Such conditions may include, but are not limited to, pointing the camera away or
200 limiting or prohibiting the use of certain devices. If conditions are placed on consent, then
201 electronic monitoring shall be conducted according to those conditions.

202 U. The facility shall conspicuously post and maintain a notice at the entrance to the resident's
203 room stating that an electronic monitoring device is in operation.

204 V. Facilities shall notify all staff and their OLC Long Term Care Supervisor that electronic
205 monitoring is in use.

206 W. A facility shall prohibit staff from covert monitoring in violation of this chapter. Facilities
207 shall instruct the resident or the resident's responsible party of this prohibition and shall provide
208 the resident or the resident's responsible party with the OLC's Complaint Hotline telephone
209 number.

210 X. If covert monitoring is discovered, the facility may require a resident or a resident's
211 responsible party to meet all the requirements for authorized monitoring prior to the continuation
212 of monitoring.

213 Y. Each nursing facility, including those that choose not to offer electronic monitoring, shall
214 adopt policies and procedures for electronic monitoring. These policies and procedures shall
215 address all the elements of this section, 12VAC5-371-191.

216 Z. A facility shall prohibit staff from tampering with electronic monitoring in violation of
217 this chapter. Facilities shall instruct the resident or the resident's responsible party of this
218 prohibition and shall provide the resident or the resident's responsible party with the OLC's
219 Complaint Hotline telephone number.



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: May 10, 2017

TO: Virginia State Board of Health

FROM: Erik Bodin, Director, Office of Licensure and Certification

SUBJECT: State Medical Facilities Plan (12VAC5-230)

Enclosed for your review are proposed amendments to the State Medical Facilities Plan (SMFP) (12VAC5-230).

The SMFP provides the service-specific criteria for the review of applications for certificate of public need (COPN), with individual sections addressing each of the various services and equipment subject to COPN. Following a periodic review of the regulations, it was determined that the Cardiac Catheterization and Nursing Home sections of the SMFP should be amended. The Notice of Intended Regulatory Action (NOIRA) stage ended in July 2015.

In drafting the amendments VDH convened two workgroups, long term care and cardiac catheterization, to provide technical input. The workgroups met numerous times and workgroup members provided consensus recommendations regarding the regulatory language. VDH reviewed the recommendations of the workgroup and from that information, VDH drafted the proposed amending language, which is presented to the Board.

The Board of Health is requested to approve the proposed amendments. Should the Board of Health approve the proposed amendments, they 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 amendments will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website and there will be a 60-day public comment period. After assessment of the public comments, any necessary changes will be made to the proposed amendments and they will come before the Board again, as final amendments.



townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-230
Regulation title(s)	State Medical Facilities Plan
Action title	Update the regulatory chapter following periodic review
Date this document prepared	May 10, 2017

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.

This regulatory action will update the regulatory chapter pertaining to the State Medical Facilities Plan in order to correct several definitions in relation to cardiac catheterization, and add some new definitions. It will also make the appropriate changes to the occupancy standard utilized for determining the need for new nursing home beds.

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.

There are no technical terms or acronyms utilized in this document.

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 § 32.1-102.2 of the Code of Virginia. Section 32.1-102.2 of the Code of Virginia requires the Board promulgate regulations which establish concise procedures for the prompt review of applications for certificates of public need consistent with Article 1.1 of Chapter 4 of Title 32.1. Section 32.1-102.2 of the Code of Virginia further requires the Board to promulgate regulations which establish specific criteria for determining need in rural areas, giving due consideration to distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care in such areas.

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.

It is necessary to amend these regulations to update definitions within the regulations related to cardiac catheterization and update the occupancy standard utilized for determining the need for new nursing home beds.

Updated regulations to implement the State Medical Facilities Plan are essential to protect the health of Virginians as the Department has determined that excess capacity or underutilization of medical facilities are detrimental to both cost effectiveness and quality of medical services in Virginia; the Department seeks to promote the availability and accessibility of proven technologies through planned geographical distribution of medical facilities; the Department seeks to promote the development and maintenance of services and access to those services by all Virginians who need them without respect to their ability to pay; the Department seeks to encourage the conversion of facilities to new and efficient uses and the reallocation of resources to meet evolving community needs; and the Department discourages the proliferation of services that would undermine the ability of essential community providers to maintain their financial viability.

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.

This regulatory action:

- Amends the existing definitions for "Cardiac Catheterization" and "Diagnostic Equivalent Procedure (DEP)".
- Adds new definitions for "Diagnostic Cardiac Catheterization", "Complex Therapeutic Cardiac Catheterization", and "Simple Therapeutic Cardiac Catheterization".
- Establishes requirements for proposals to provide simple and complex therapeutic cardiac catheterization.

- Amends requirements for calculating need for additional nursing facility beds in a health planning district by requiring the analysis of both the average and median occupancy levels of Medicaid-certified nursing facility beds.
- Reduces the occupancy level required to approve expansion of beds in an existing nursing facility from 93 percent to 90 percent.

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 that the criteria for demonstrating public need for the included facilities will more closely reflect changes in technology, as well as application of service and utilization patterns, and will therefore help increase access to the services for the citizens of the Commonwealth. The Virginia Department of Health does not foresee any disadvantages to the public. The primary advantage to the agency and the Commonwealth is the promotion of access to health care services. There are no disadvantages associated with the proposed regulatory action in relation to the agency or 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 federal requirements related to certificate of public need (COPN)

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 shall be particularly affected by the proposed amendments. No particular locality shall bear any identified disproportionate material impact which would not be experienced by other localities.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also

seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so by mail, email, or fax to **Domica Winstead, Policy Analyst, 9960 Mayland Drive Suite 401, Richmond, Virginia 23233, phone: 804-367-2157, and email: Domica.Winstead@vdh.virginia.gov** or via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>). Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

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

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.	Individuals or businesses that own medical care facilities subject to COPN review. More specifically, inpatient acute care hospitals and nursing homes, as well as those proposing to develop inpatient acute care hospitals and nursing homes.
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.	105 hospitals currently provide, or may seek to provide at some time in the future, cardiac catheterization services. 284 existing nursing homes and an unknown number of future applicants for the development of nursing homes in the Commonwealth.
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 additional costs are anticipated for affected entities to comply with the amended regulations over the current cost to comply.

<p>Beneficial impact the regulation is designed to produce.</p>	<p>The proposed amendments to the regulation are not expected to have any economic impact.</p> <p>The amendments to the cardiac catheterization provisions are designed to help improve clinical service quality. The amendments to the nursing facility provisions are designed to provide a more accurate assessment of need for additional nursing facility beds in each health planning district, in response to federal policy changes that have resulted in shortened average lengths of stay and reduced occupancy levels. Specifically, the Centers for Medicare and Medicaid Services now pay for short-stay rehabilitation patients in nursing facilities, which has served to help reduce average length of stays and occupancy levels.</p>
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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 intended regulatory action to carry out the Board's statutory mandate to promulgate regulations which establish concise procedures for the prompt review of applications for certificates of public need consistent with Article 1.1 of Chapter 4 of Title 32.1 and regulations which establish specific criteria for determining need in rural areas, giving due consideration to distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care in such areas. The regulations are mandated by § 32.1-102.2 of the Code of Virginia.

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 proposed amendments are clearly and directly mandated by law. The alternative regulatory methods are not permitted due to the statutory mandate.

Periodic review and small business impact review report of findings

If you are using this form to report the result of a periodic review/small business impact review that was announced during the NOIRA stage, please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

The regulation meets the criteria set out in Executive Order 17 (2014) as the regulation is necessary for the protection of public health, safety and welfare and is clearly written and easily understandable. There is a continued need for the regulation as the regulation is required by § 32.1-102.2 of the Code of Virginia. The Department has not received complaints from the public concerning the regulation. The regulatory chapter is written as simply as possible. The regulation does not overlap, duplicate or conflict with any federal or state law or regulation. The regulation was reviewed and evaluated during the periodic review held from April 22, 2013 until May 14, 2013. The proposed amendments address factors which have changed in the area affected by the regulation.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response

No public comment was received during the public comment period following the publication of the NOIRA.

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 regulatory action 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 follow the instructions in the text following the three chart templates below

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-230-10-Definitions		"Cardiac catheterization" means a procedure where a flexible tube is inserted into the patient through an extremity blood vessel and advanced under fluoroscopic guidance into the heart chambers. Cardiac catheterization may include therapeutic intervention, but does not include a simple right heart catheterization for monitoring purposes as might be performed in an electrophysiology laboratory, pulmonary angiography as an isolated procedure, or cardiac pacing through a right electrode catheter.	<p>"Cardiac catheterization" means <u>an invasive procedure</u> where a flexible tube is inserted into the patient through an extremity blood vessel and advanced under fluoroscopic guidance into the heart chambers or <u>coronary arteries</u>. A Ccardiac catheterization may <u>be conducted for diagnostic and/or therapeutic purposes</u> include therapeutic intervention, but does not include a simple right heart catheterization for monitoring purposes as might be performed in an electrophysiology laboratory, pulmonary angiography as an isolated procedure, or cardiac pacing through a right electrode catheter.</p> <p>Intent: To clarify the language and to designate cardiac catheterizations as either diagnostic or therapeutic.</p> <p>Likely Impact: Provides clarification for language proposed in the regulations.</p>
12VAC5-230-10-Definitions		N/A	<p><u>"Complex therapeutic cardiac catheterization"</u> means the performance of cardiac catheterization for the purpose of correcting or improving certain conditions that have been determined to exist in the heart or <u>great arteries or veins of the heart, specifically catheter-based procedures for structural treatment to correct congenital or acquired structural or valvular abnormalities.</u></p> <p>Intent: To bring the regulations up to date with current cardiac catheterization practices.</p>

			<p>Likely Impact: Provides clarification for language proposed in the regulations.</p>
12VAC5-230-10-Definitions		<p>"DEP" means diagnostic equivalent procedure, a method for weighing the relative value of various cardiac catheterization procedures as follows: a diagnostic procedure equals 1 DEP, a therapeutic procedure equals 2 DEPs, a same session procedure (diagnostic and therapeutic) equals 3 DEPs, and a pediatric procedure equals 2 DEPs.</p>	<p>"DEP" means diagnostic equivalent procedure, a method for weighing the relative value of various cardiac catheterization procedures as follows: a diagnostic <u>cardiac catheterization</u> equals 1 DEP, a <u>simple therapeutic cardiac catheterization</u> equals 2 DEPs, a same session procedure (diagnostic and <u>simple therapeutic</u>) equals 3 DEPs, and a pediatric procedure equals 2 DEPs and a <u>complex therapeutic cardiac catheterization</u> equals 5 DEPs. <u>A multiplier of 2 will be applied for a pediatric procedure (i.e. a pediatric simple diagnostic cardiac catheterization equals 2 DEPs, a pediatric simple therapeutic cardiac catheterization equals 4 DEPs, and a pediatric complex therapeutic cardiac catheterization equals 10 DEPs.)</u></p> <p>Intent: To more appropriately apply diagnostic equivalent procedure calculations to differentiate between the relative value of different acuity level and severity of different types of cardiac catheterization procedures.</p> <p>Likely Impact: Provides clarification for language proposed in the regulations.</p>
12VAC5-230-10-Definitions		N/A	<p><u>"Diagnostic cardiac catheterization" means the performance of cardiac catheterization for the purpose of detecting and identifying defects in the great arteries or veins of the heart, or abnormalities in the heard structure, whether congenital or acquired.</u></p> <p>Intent: To define diagnostic cardiac catheterization as opposed to therapeutic cardiac catheterizations.</p> <p>Likely Impact: Provides clarification for language proposed in the regulations.</p>

<p>12VAC5-230-10-Definitions</p>		<p>N/A</p>	<p><u>“Simple therapeutic cardiac catheterization” means the performance of cardiac catheterization for the purpose of correcting or improving certain conditions that have been determined to exist in the heart, specifically catheter-based treatment procedures for relieving coronary artery narrowing.</u></p> <p>Intent: To bring the regulations up to date with current cardiac catheterization practices.</p> <p>Likely Impact: Provides clarification for language proposed in the regulations.</p>
<p>12VAC5-230-420. Nonemergent cardiac catheterization</p>		<p>Proposals to provide elective interventional cardiac procedures such as PTCA, transseptal puncture, transthoracic left ventricle puncture, myocardial biopsy or any valvuloplasty procedures, diagnostic pericardiocentesis or therapeutic procedures should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed non-emergent cardiac service will be located.</p>	<p>Proposals to provide elective interventional cardiac procedures such as PTCA, transseptal puncture, transthoracic left ventricle puncture, myocardial biopsy or any valvuloplasty procedures, diagnostic pericardiocentesis or therapeutic procedures should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed non-emergent cardiac service will be located.</p> <p><u>A. Simple therapeutic cardiac catheterization: Proposals to provide simple therapeutic cardiac catheterization are not required to offer open heart surgery service available on-site in the same hospital in which the proposed simple therapeutic service will be located. However, these programs will be expected to adhere to the following guidelines based on the most recent version of the American Heart Association/American Stroke Association’s Percutaneous Coronary Intervention (PCI) without Surgical Back-up Policy Guidance:</u></p> <p><u>Participation in the Virginia Cardiac Services Quality Initiative as well as the Action Registry-Get With the Guideline (AR-G) and/or National Cardiovascular Data Registry (NCDR) to monitor quality and outcomes;</u> <u>adherence to strict patient-selection criteria;</u> <u>annual institutional volumes of 300 cardiac catheterization procedures, of which at least 75 should be PCI (or as dictated by American Heart Association</u></p>

			<p><u>(AHA)/American College of Cardiology (ACC) guidelines):</u> <u>use of only AHA/ACC-qualified operators who meet the standards for training and competency;</u> <u>demonstration of appropriate planning for program development and completion of both a primary PCI development program and an elective PCI development program which includes routine care process and case selection review;</u> <u>development and maintenance of a quality and error management program;</u> <u>provision of PCI 24 hours a day, 7 days a week;</u> <u>development and maintenance of necessary agreements with a tertiary facility (which must agree to accept emergent and non-emergent transfers for additional medical care, cardiac surgery, or intervention);</u> <u>development and maintenance of agreements with an ambulance service capable of advanced life support and intra-aortic balloon pump (IABP) transfer that guarantees a 30-minute-or less response time; and</u> <u>participation in the Virginia Heart Attack Council and the Virginia Cardiac Services Quality Initiative</u></p> <p>Intent: To list the circumstances under which a facility can provide simple therapeutic cardiac catheterizations.</p> <p>Likely Impact: This will prevent hospitals without open heart surgery back up from performing complex therapeutic catheterizations.</p> <p><u>B. Complex therapeutic cardiac catheterization: Proposals to provide complex therapeutic cardiac catheterization should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed complex therapeutic service will be located. Additionally, these complex therapeutic cardiac catheterization programs will be required to participate in the Virginia Cardiac Services Quality Initiative and the Virginia Heart Attack Council.</u></p> <p>Intent: To list circumstances under which a facility can provide complex therapeutic cardiac catheterizations.</p>
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			<p>Likely Impact: This will allow hospitals that meet the required standards to perform complex therapeutic cardiac catheterizations.</p>
<p>12VAC5-230-610. Need for new service</p>		<p>A. A health planning district should be considered to have a need for additional nursing facility beds when:</p> <ol style="list-style-type: none"> 1. The bed need forecast exceeds the current inventory of beds for the health planning district; and 2. The average annual occupancy of all existing and authorized Medicaid-certified nursing facility beds in the health planning district was at least 93%, excluding the bed inventory and utilization of the Virginia Veterans Care Centers. <p>Exception: When there are facilities that have been in operation less than three years in the health planning district, their occupancy can be excluded from the calculation of average occupancy if the facilities had an annual occupancy of at least 93% in one of its first three years of operation.</p> <p>B. No health planning district should be considered in need of additional beds if there are unconstructed beds designated as Medicaid-certified. This presumption of 'no need' for additional beds extends for three years from the issuance date of the certificate.</p> <p>C. The bed need forecast will be computed as follows:</p> $PDBN = (UR64 \times PP64) + (UR69 \times PP69) + (UR74 \times PP74) + (UR79 \times PP79) + (UR84 \times PP84) + (UR85 \times PP85)$	<p>A. A health planning district should be considered to have a need for additional nursing facility beds when:</p> <ol style="list-style-type: none"> 1. The bed need forecast exceeds the current inventory of <u>existing and authorized</u> beds for the health planning district; and <p>Intent: To clarify that authorized but non-operational beds should be included in the inventory for health planning districts.</p> <p>Likely Impact: This will allow for a more accurate forecast of net need.</p> <ol style="list-style-type: none"> 2. The average median annual occupancy of all existing and authorized Medicaid-certified nursing facility beds in the health planning district was at least 93.0%, <u>and the average annual occupancy of all existing and authorized Medicaid-certified nursing facility beds in the health planning district was at least 90.0%</u>, excluding the bed inventory and utilization of the Virginia Veterans Care Centers. <p>Exception: When there are facilities that have been in operation less than three one years in the health planning district, their occupancy can shall be excluded from the calculation of average occupancy if the facilities had an annual occupancy of at least 93% in one of its first three years of operation.</p> <p>Intent: The proposed changes to the calculation of need will smooth the assessment of individual planning districts by contrasting average utilization with median occupancy, which reduces the influence of facility outliers at both ends of the spectrum.</p> <p>Likely Impact: A more accurate assessment of need for additional nursing home beds will be made for each planning district.</p> <p>B. No health planning district should be considered in need of additional beds if there are unconstructed beds designated</p>

		<p>Where:</p> <p>PDBN = Planning district bed need.</p> <p>UR64 = The nursing home bed use rate of the population aged 0 to 64 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP64 = The population aged 0 to 64 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.</p> <p>UR69 = The nursing home bed use rate of the population aged 65 to 69 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP69 = The population aged 65 to 69 projected for the health planning district three years from the current year as most recently published by the a demographic program as determined by the commissioner.</p> <p>UR74 = The nursing home bed use rate of the population aged 70 to 74 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP74 = The population aged 70 to 74 projected for the health planning district three years from the current year as most recently published by a demographic program as</p>	<p>as Medicaid-certified. This presumption of 'no need' for additional beds extends for three years from the issuance date of the certificate.</p> <p>C. The bed need forecast will be computed as follows:</p> $PDBN = (UR64 \times PP64) + (UR69 \times PP69) + (UR74 \times PP74) + (UR79 \times PP79) + (UR84 \times PP84) + (UR85 \times PP85)$ <p>Where:</p> <p>PDBN = Planning district bed need.</p> <p>UR64 = The nursing home bed use rate of the population aged 0 to 64 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP64 = The population aged 0 to 64 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.</p> <p>UR69 = The nursing home bed use rate of the population aged 65 to 69 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP69 = The population aged 65 to 69 projected for the health planning district three years from the current year as most recently published by the a demographic program as determined by the commissioner.</p> <p>UR74 = The nursing home bed use rate of the population aged 70 to 74 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP74 = The population aged 70 to 74 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.</p> <p>UR79 = The nursing home bed use rate of the population aged 75 to 79 in the health</p>
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		<p>determined by the commissioner.</p> <p>UR79 = The nursing home bed use rate of the population aged 75 to 79 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP79 = The population aged 75 to 79 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.</p> <p>UR84 = The nursing home bed use rate of the population aged 80 to 84 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP84 = The population aged 80 to 84 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.</p> <p>UR85+ = The nursing home bed use rate of the population aged 85 and older in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP85+ = The population aged 85 and older projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.</p>	<p>planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP79 = The population aged 75 to 79 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.</p> <p>UR84 = The nursing home bed use rate of the population aged 80 to 84 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP84 = The population aged 80 to 84 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.</p> <p>UR85+ = The nursing home bed use rate of the population aged 85 and older in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.</p> <p>PP85+ = The population aged 85 and older projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.</p> <p>Health planning district bed need forecasts will be rounded as follows:</p> <p>Health Planning District Bed Need Rounded Bed Need</p> <table border="0"> <tr> <td>1-29</td> <td>0</td> </tr> <tr> <td>30-44</td> <td>30</td> </tr> <tr> <td>45-84</td> <td>60</td> </tr> <tr> <td>85-104</td> <td>90</td> </tr> <tr> <td>105-134</td> <td>120</td> </tr> <tr> <td>135-164</td> <td>150</td> </tr> <tr> <td>165-194</td> <td>180</td> </tr> </table>	1-29	0	30-44	30	45-84	60	85-104	90	105-134	120	135-164	150	165-194	180
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<p>12VAC5-230-620. Expansion of services</p>		<p>Proposals to increase existing nursing facility bed capacity should not be approved unless the facility has operated for at least two years and the average annual occupancy of the facility's existing beds was at least 93% in the relevant reporting period as reported to VHI.</p> <p>Note: Exceptions will be considered for facilities that operated at less than 93% average annual occupancy in the most recent year for which bed utilization has been reported when the facility offers short stay services causing an average annual occupancy lower than 93% for the facility.</p>	<p>Proposals to increase <u>an</u> existing nursing facility's bed capacity should not be approved unless the facility has operated for at least two years and the average annual occupancy of the facility's existing beds was at least 93% <u>90.0%</u> in the relevant reporting period as reported to VHI.</p> <p>Note: Exceptions will be considered for facilities that operated at less than 93% <u>90.0%</u> average annual occupancy in the most recent year for which bed utilization has been reported when the facility offers short stay services causing an average annual occupancy lower than 93% <u>90.0%</u> for the facility.</p> <p>Intent: To allow for an increase the lead time needed for the development and construction of new nursing homes.</p> <p>Likely Impact: Lower threshold occupancy will result in a determination of need for the planning district earlier, allowing for more time to develop the new facility.</p>

Chapter 230 - STATE MEDICAL FACILITIES PLAN
Part I
Definitions and General Information

1 12VAC5-230-10. Definitions.

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

4 "Acute psychiatric services" means hospital-based inpatient psychiatric services provided in distinct
5 inpatient units in general hospitals or freestanding psychiatric hospitals.

6 "Acute substance abuse disorder treatment services" means short-term hospital-based inpatient treatment
7 services with access to the resources of (i) a general hospital, (ii) a psychiatric unit in a general hospital,
8 (iii) an acute care addiction treatment unit in a general hospital licensed by the Department of Health, or
9 (iv) a chemical dependency specialty hospital with acute care medical and nursing staff and life support
10 equipment licensed by the Department of Mental Health, Mental Retardation and Substance Abuse
11 Services.

12 "Bassinet" means an infant care station, including warming stations and isolettes.

13 "Bed" means that unit, within the complement of a medical care facility, subject to COPN review as
14 required by § 32.1-102.1 of the Code of Virginia and designated for use by patients of the facility or
15 service. For the purposes of this chapter, bed does include cribs and bassinets used for pediatric patients,
16 but does not include cribs and bassinets in the newborn nursery or neonatal special care setting.

17 "Cardiac catheterization" means an invasive procedure where a flexible tube is inserted into the patient
18 through an extremity blood vessel and advanced under fluoroscopic guidance into the heart chambers or
19 coronary arteries. A ~~C~~cardiac catheterization may be conducted for diagnostic and/or therapeutic
20 purposes ~~include therapeutic intervention~~, but does not include a simple right heart catheterization for
21 monitoring purposes as might be performed in an electrophysiology laboratory, pulmonary angiography
22 as an isolated procedure, or cardiac pacing through a right electrode catheter.

23 "Commissioner" means the State Health Commissioner.

24 "Competing applications" means applications for the same or similar services and facilities that are
25 proposed for the same health planning district, or same health planning region for projects reviewed on a
26 regional basis, and are in the same batch review cycle.

27 "Complex therapeutic cardiac catheterization" means the performance of cardiac catheterization for the
28 purpose of correcting or improving certain conditions that have been determined to exist in the heart or
29 great arteries or veins of the heart, specifically catheter-based procedures for structural treatment to
30 correct congenital or acquired structural or valvular abnormalities.

31 "Computed tomography" or "CT" means a noninvasive diagnostic technology that uses computer analysis
32 of a series of cross-sectional scans made along a single axis of a bodily structure or tissue to construct an
33 image of that structure.

34 "Continuing care retirement community" or "CCRC" means a retirement community consistent with the
35 requirements of Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.

36 "COPN" means a Medical Care Facilities Certificate of Public Need for a project as required in Article
37 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

38 "COPN program" means the Medical Care Facilities Certificate of Public Need Program implementing
39 Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

40 "DEP" means diagnostic equivalent procedure, a method for weighing the relative value of various
41 cardiac catheterization procedures as follows: a diagnostic cardiac catheterization equals 1 DEP, a simple
42 therapeutic cardiac catheterization equals 2 DEPs, a same session procedure (diagnostic and simple
43 therapeutic) equals 3 DEPs, ~~and a pediatric procedure equals 2 DEPs and a complex therapeutic cardiac~~
44 catheterization equals 5 DEPs. A multiplier of 2 will be applied for a pediatric procedure (i.e. a pediatric
45 simple diagnostic cardiac catheterization equals 2 DEPs, a pediatric simple therapeutic cardiac
46 catheterization equals 4 DEPs, and a pediatric complex therapeutic cardiac catheterization equals 10
47 DEPs.)

48 "Diagnostic cardiac catheterization" means the performance of cardiac catheterization for the purpose of
49 detecting and identifying defects in the great arteries or veins of the heart, or abnormalities in the heard
50 structure, whether congenital or acquired.

51 "Direction" means guidance, supervision or management of a function or activity.

52 "Gamma knife®" means the name of a specific instrument used in stereotactic radiosurgery.

53 "Health planning district" means the same contiguous areas designated as planning districts by the
54 Virginia Department of Housing and Community Development or its successor.

55 "Health planning region" means a contiguous geographic area of the Commonwealth as designated by the
56 Board of Health with a population base of at least 500,000 persons, characterized by the availability of
57 multiple levels of medical care services, reasonable travel time for tertiary care, and congruence with
58 planning districts.

59 "Health system" means an organization of two or more medical care facilities, including but not limited to
60 hospitals, that are under common ownership or control and are located within the same health planning
61 district, or health planning region for projects reviewed on a regional basis.

62 "Hospital" means a medical care facility licensed as an inpatient hospital or outpatient surgical center by
63 the Department of Health or as a psychiatric hospital by the Department of Mental Health, Mental
64 Retardation, and Substance Abuse Services.

65 "ICF/MR" means an intermediate care facility for the mentally retarded.

66 "Indigent" means any person whose gross family income is equal to or less than 200% of the federal
67 Nonfarm Poverty Level or income levels A through E of 12VAC5-200-10 and who is uninsured.

68 "Inpatient" means a patient who is hospitalized longer than 24 hours for health or health related services.

69 "Intensive care beds" or "ICU" means inpatient beds located in the following units or categories:

70 1. General intensive care units are those units where patients are concentrated by reason of serious illness
71 or injury regardless of diagnosis. Special lifesaving techniques and equipment are immediately available
72 and patients are under continuous observation by nursing staff;

73 2. Cardiac care units, also known as Coronary Care Units or CCUs, are units staffed and equipped solely
74 for the intensive care of cardiac patients; and

75 3. Specialized intensive care units are any units with specialized staff and equipment for the purpose of
76 providing care to seriously ill or injured patients based on age selected categories of diagnoses, including
77 units established for burn care, trauma care, neurological care, pediatric care, and cardiac surgery
78 recovery, but does not include bassinets in neonatal special care units.

79 "Lithotripsy" means a noninvasive therapeutic procedure to (i) crush renal and biliary stones using shock
80 waves, i.e., renal lithotripsy or (ii) treat certain musculoskeletal conditions and to relieve the pain
81 associated with tendonitis, i.e., orthopedic lithotripsy.

82 "Long-term acute care hospital" or "LTACH" means an inpatient hospital that provides care for patients
83 who require a length of stay greater than 25 days and is, or proposes to be, certified by the Centers for
84 Medicare and Medicaid Services as a long-term care inpatient hospital pursuant to 42 CFR Part 412. An
85 LTACH may be either a free standing facility or located within an existing or host hospital.

86 "Magnetic resonance imaging" or "MRI" means a noninvasive diagnostic technology using a nuclear
87 spectrometer to produce electronic images of specific atoms and molecular structures in solids, especially
88 human cells, tissues and organs.

89 "Medical rehabilitation" means those services provided consistent with 42 CFR 412.23 and 412.24.

90 "Medical/surgical" means those services available for the care and treatment of patients not requiring
91 specialized services.

92 "Minimum survival rates" means the base percentage of transplant recipients who survive at least one
93 year or for such other period of time as specified by the United Network for Organ Sharing (UNOS).

94 "Neonatal special care" means care for infants in one or more of the higher service levels designated in
95 12VAC5-410-443 of the Rules and Regulations for the Licensure of Hospitals.

96 "Nursing facility" means those facilities or components thereof licensed to provide long-term nursing
97 care.

98 "Obstetrical services" means the distinct organized program, equipment and care related to pregnancy and
99 the delivery of newborns in inpatient facilities.

100 "Off-site replacement" means the relocation of existing beds or services from an existing medical care
101 facility site to another location within the same health planning district.

102 "Open heart surgery" means a surgical procedure requiring the use or immediate availability of a heart-
103 lung bypass machine or "pump." The use of the pump during the procedure distinguishes "open heart"
104 from "closed heart" surgery.

105 "Operating room" means a room used solely or principally for the provision of surgical procedures
106 involving the administration of anesthesia, multiple personnel, recovery room access, and a fully
107 controlled environment.

108 "Operating room use" means the amount of time a patient occupies an operating room and includes room
109 preparation and cleanup time.

110 "Operating room visit" means one session in one operating room in an inpatient hospital or outpatient
111 surgical center, which may involve several procedures. Operating room visit may be used interchangeably
112 with "operation" or "case."

113 "Outpatient" means a patient who visits a hospital, clinic, or associated medical care facility for diagnosis
114 or treatment, but is not hospitalized 24 hours or longer.

115 "Pediatric" means patients younger than 18 years of age. Newborns in nurseries are excluded from this
116 definition.

117 "Perinatal services" means those resources and capabilities that all hospitals offering general level
118 newborn services as described in 12VAC5-410-443 of the Rules and Regulations for the Licensure of
119 Hospitals must provide routinely to newborns.

120 "PET/CT scanner" means a single machine capable of producing a PET image with a concurrently
121 produced CT image overlay to provide anatomic definition to the PET image. For the purpose of granting
122 a COPN, the Board of Health pursuant to § 32.1-102.2 A 6 of the Code of Virginia has designated
123 PET/CT as a specialty clinical service. A PET/CT scanner shall be reviewed under the PET criteria as an
124 enhanced PET scanner unless the CT unit will be used independently. In such cases, a PET/CT scanner
125 that will be used to take independent PET and CT images will be reviewed under the applicable PET and
126 CT services criteria.

127 "Planning horizon year" means the particular year for which bed or service needs are projected.

128 "Population" means the census figures shown in the most current series of projections published by a
129 demographic entity as determined by the commissioner.

130 "Positron emission tomography" or "PET" means a noninvasive diagnostic or imaging modality using the
131 computer-generated image of local metabolic and physiological functions in tissues produced through the
132 detection of gamma rays emitted when introduced radio-nuclides decay and release positrons. A PET
133 device or scanner may include an integrated CT to provide anatomic structure definition.

134 "Primary service area" means the geographic territory from which 75% of the patients of an existing
135 medical care facility originate with respect to a particular service being sought in an application.

136 "Procedure" means a study or treatment or a combination of studies and treatments identified by a distinct
137 ICD-9 or CPT code performed in a single session on a single patient.

138 "Qualified" means meeting current legal requirements of licensure, registration or certification in Virginia
139 or having appropriate training, including competency testing, and experience commensurate with
140 assigned responsibilities.

141 "Radiation therapy" means treatment using ionizing radiation to destroy diseased cells and for the relief of
142 symptoms. Radiation therapy may be used alone or in combination with surgery or chemotherapy.

143 "Relevant reporting period" means the most recent 12-month period, prior to the beginning of the
144 applicable batch review cycle, for which data is available from VHI or a demographic entity as
145 determined by the commissioner.

146 "Rural" means territory, population, and housing units that are classified as "rural" by the Bureau of the
147 Census of the United States Department of Commerce, Economic and Statistics Administration.

148 "Simple therapeutic cardiac catheterization" means the performance of cardiac catheterization for the
149 purpose of correcting or improving certain conditions that have been determined to exist in the heart,
150 specifically catheter-based treatment procedures for relieving coronary artery narrowing.

151 "SMFP" means the state medical facilities plan as contained in Article 1.1 (§ 32.1-102.1 et seq.) of
152 Chapter 4 of Title 32.1 of the Code of Virginia used to make medical care facilities and services needs
153 decisions.

154 "Stereotactic radiosurgery" or "SRS" means the use of external radiation in conjunction with a stereotactic
155 guidance device to very precisely deliver a therapeutic dose to a tissue volume. SRS may be delivered in a
156 single session or in a fractionated course of treatment up to five sessions.

157 "Stereotactic radiotherapy" or "SRT" means more than one session of stereotactic radiosurgery.

158 "Substance abuse disorder treatment services" means services provided to individuals for the prevention,
159 diagnosis, treatment, or palliation of chemical dependency, which may include attendant medical and
160 psychiatric complications of chemical dependency. Substance abuse disorder treatment services are
161 licensed by the Department of Mental Health, Mental Retardation and Substance Abuse Services.

162 "Supervision" means to direct and watch over the work and performance of others.

163 "Use rate" means the rate at which an age cohort or the population uses medical facilities and services.
164 The rates are determined from periodic patient origin surveys conducted for the department by the
165 regional health planning agencies, or other health statistical reports authorized by Chapter 7.2 (§ 32.1-
166 276.2 et seq.) of Title 32.1 of the Code of Virginia.

167 "VHI" means the health data organization defined in § 32.1-276.4 of the Code of Virginia and under
168 contract with the Virginia Department of Health.

Part IV
Cardiac Services
Article 1
Criteria and Standards for Cardiac Catheterization Services

169 12VAC5-230-420. Nonemergent cardiac catheterization.

170 ~~Proposals to provide elective interventional cardiac procedures such as PTCA, transseptal puncture,~~
171 ~~transthoracic left ventricle puncture, myocardial biopsy or any valvuloplasty procedures, diagnostic~~
172 ~~pericardiocentesis or therapeutic procedures should be approved only when open heart surgery services~~
173 ~~are available on-site in the same hospital in which the proposed non-emergent cardiac service will be~~
174 ~~located.~~

175 A. Simple therapeutic cardiac catheterization: Proposals to provide simple therapeutic cardiac
176 catheterization are not required to offer open heart surgery service available on-site in the same
177 hospital in which the proposed simple therapeutic service will be located. However, these programs
178 will be expected to adhere to the following guidelines based on the most recent version of the
179 American Heart Association/American Stroke Association's Percutaneous Coronary Intervention
180 (PCI) without Surgical Back-up Policy Guidance:

- 181 • Participation in the Virginia Cardiac Services Quality Initiative as well as the Action
182 Registry-Get With the Guideline (AR-G) and/or National Cardiovascular Data Registry
183 (NCDR) to monitor quality and outcomes;
- 184 • adherence to strict patient-selection criteria;
- 185 • annual institutional volumes of 300 cardiac catheterization procedures, of which at least 75
186 should be PCI (or as dictated by American Heart Association (AHA)/American College of
187 Cardiology (ACC) guidelines);
- 188 • use of only AHA/ACC-qualified operators who meet the standards for training and
189 competency;
- 190 • demonstration of appropriate planning for program development and completion of both a
191 primary PCI development program and an elective PCI development program which includes
192 routine care process and case selection review;
- 193 • development and maintenance of a quality and error management program;
- 194 • provision of PCI 24 hours a day, 7 days a week;
- 195 • development and maintenance of necessary agreements with a tertiary facility (which must
196 agree to accept emergent and non-emergent transfers for additional medical care, cardiac
197 surgery, or intervention);

- 218 • development and maintenance of agreements with an ambulance service capable of advanced
- 219 life support and intra-aortic balloon pump (IABP) transfer that guarantees a 30-minute-or less
- 220 response time; and
- 221 • participation in the Virginia Heart Attack Council and the Virginia Cardiac Services Quality
- 222 Initiative
- 223 B. Complex therapeutic cardiac catheterization: Proposals to provide complex therapeutic cardiac
- 224 catheterization should be approved only when open heart surgery services are available on-site in the
- 225 same hospital in which the proposed complex therapeutic service will be located. Additionally, these
- 226 complex therapeutic cardiac catheterization programs will be required to participate in the Virginia
- 227 Cardiac Services Quality Initiative and the Virginia Heart Attack Council.

Part VII
Nursing Facilities

228 12VAC5-230-610. Need for new service.

229 A. A health planning district should be considered to have a need for additional nursing facility beds
230 when:

231 1. The bed need forecast exceeds the current inventory of existing and authorized beds for the health
232 planning district; and

233 2. The average median annual occupancy of all existing and authorized Medicaid-certified nursing facility
234 beds in the health planning district was at least 93.0%, and the average annual occupancy of all existing
235 and authorized Medicaid-certified nursing facility beds in the health planning district was at least 90.0%,
236 excluding the bed inventory and utilization of the Virginia Veterans Care Centers.

237 Exception: When there are facilities that have been in operation less than ~~three~~ one years in the health
238 planning district, their occupancy ~~can~~ shall be excluded from the calculation of average occupancy ~~if the~~
239 ~~facilities had an annual occupancy of at least 93% in one of its first three years of operation.~~

240 B. No health planning district should be considered in need of additional beds if there are unconstructed
241 beds designated as Medicaid-certified. This presumption of 'no need' for additional beds extends for three
242 years from the issuance date of the certificate.

243 C. The bed need forecast will be computed as follows:

$$244 \text{PDBN} = (\text{UR64} \times \text{PP64}) + (\text{UR69} \times \text{PP69}) + (\text{UR74} \times \text{PP74}) + (\text{UR79} \times \text{PP79}) + (\text{UR84} \times \text{PP84}) +$$

$$245 (\text{UR85} \times \text{PP85})$$

246 Where:

247 PDBN = Planning district bed need.

248 UR64 = The nursing home bed use rate of the population aged 0 to 64 in the health planning district as
249 determined in the most recent nursing home patient origin study authorized by VHI.

230 PP64 = The population aged 0 to 64 projected for the health planning district three years from the current
231 year as most recently published by a demographic program as determined by the commissioner.

232 UR69 = The nursing home bed use rate of the population aged 65 to 69 in the health planning district as
233 determined in the most recent nursing home patient origin study authorized by VHI.

234 PP69 = The population aged 65 to 69 projected for the health planning district three years from the
235 current year as most recently published by the a demographic program as determined by the
236 commissioner.

237 UR74 = The nursing home bed use rate of the population aged 70 to 74 in the health planning district as
238 determined in the most recent nursing home patient origin study authorized by VHI.

239 PP74 = The population aged 70 to 74 projected for the health planning district three years from the
240 current year as most recently published by a demographic program as determined by the commissioner.

241 UR79 = The nursing home bed use rate of the population aged 75 to 79 in the health planning district as
242 determined in the most recent nursing home patient origin study authorized by VHI.

243 PP79 = The population aged 75 to 79 projected for the health planning district three years from the
244 current year as most recently published by a demographic program as determined by the commissioner.

245 UR84 = The nursing home bed use rate of the population aged 80 to 84 in the health planning district as
246 determined in the most recent nursing home patient origin study authorized by VHI.

247 PP84 = The population aged 80 to 84 projected for the health planning district three years from the
248 current year as most recently published by a demographic program as determined by the commissioner.

249 UR85+ = The nursing home bed use rate of the population aged 85 and older in the health planning
250 district as determined in the most recent nursing home patient origin study authorized by VHI.

251 PP85+ = The population aged 85 and older projected for the health planning district three years from the
252 current year as most recently published by a demographic program as determined by the commissioner.

253 Health planning district bed need forecasts will be rounded as follows:

254 Health Planning District Bed Need

255 Rounded Bed Need

256	1-29	0
257	30-44	30
258	45-84	60
259	85-104	90
260	105-134	120
261	135-164	150
262	165-194	180
263	195-224	210
264	225+	240

265 Exception: When a health planning district has:
266 1. Two or more nursing facilities;
267 2. Had an average median annual occupancy rate ~~in excess~~ of 93.0% and an average occupancy rate of at
268 least 90.0% for each of the most recent two years for which bed utilization has been reported to VHI; and
269 3. Has a forecasted bed need of 15 to 29 beds, then the bed need for this health planning district will be
270 rounded to 30.

271 D. No new freestanding nursing facilities of less than 90 beds should be authorized. However,
272 consideration may be given to a new freestanding facility with fewer than 90 nursing facility beds when
273 the applicant can demonstrate that such a facility is justified based on a locality's preference for such
274 smaller facility and there is a documented poor distribution of nursing facility beds within the health
275 planning district.

276 E. When evaluating the capital cost of a project, consideration may be given to projects that use the
277 current methodology as determined by the Department of Medical Assistance Services.

278 F. Preference may be given to projects that replace outdated and functionally obsolete facilities with
279 modern facilities that result in the more cost-efficient resident services in a more aesthetically pleasing
280 and comfortable environment.

281 12VAC5-230-620. Expansion of services.

282 Proposals to increase an existing nursing facility's bed capacity should not be approved unless the facility
283 has operated for at least two years and the average annual occupancy of the facility's existing beds was at
284 least ~~93%~~ 90.0% in the relevant reporting period as reported to VHI.

285 Note: Exceptions will be considered for facilities that operated at less than ~~93%~~ 90.0% average annual
286 occupancy in the most recent year for which bed utilization has been reported when the facility offers
287 short stay services causing an average annual occupancy lower than ~~93%~~ 90.0% for the facility.



COMMONWEALTH of VIRGINIA

Department of Health

MARISSA J. LEVINE, MD, MPH, FAAPF
INTERIM STATE HEALTH COMMISSIONER

PO BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: April 6, 2017

TO: Virginia State Board of Health

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

SUBJECT: Fast Track Amendments to the Regulations for the Immunization of School Children

The agency is proposing to amend the Regulations for the Immunization of School Children (12VAC5-110) to respond to growing resistance to allowing health department representatives to review school immunization records, and to update references to the immunization schedule.

Specifically, 12VAC5-110-90 will incorporate language currently in § 22.1-271.2 of the Code of Virginia that requires school immunization records to be open to inspection by officials of the health department. In addition, references to the recommended immunization schedule will be changed from 2015 to 2017.

The Board of Health is asked to approve this fast track amendment at its June 1 meeting. Following approval, the proposed amendment would be submitted to the Virginia Regulatory Town Hall to initiate Executive Branch review of the proposed amendments.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Department of Health, Office of Epidemiology
Virginia Administrative Code (VAC) citation(s)	12VAC5-110
Regulation title(s)	Regulations for the Immunization of School Children
Action title	Update Immunization Schedules and Clarify Responsibilities of School Admitting Officials.
Date this document prepared	April 7, 2017

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 regulations will be amended to incorporate language from § 22.1-271.2 of the Code of Virginia to clarify that each admitting official is required to allow inspection of school immunization records by officials of the Department of Health.

The regulations will also be amended to reference the latest recommended immunization schedules.

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.

ACIP means the Advisory Committee on Immunization Practices, a group of medical and public health experts that develop recommendations on how to use vaccines to control diseases in the United States.

AAP means the American Academy of Pediatrics.

CDC means the U.S. Centers for Disease Control and Prevention

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.

Enter statement here

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.

Statutory authority to promulgate these regulations is granted to the State Board of Health by §§ 22.1-271.2 and 32.1-46 of the Code of Virginia. Penalties are established in § 32.1-27 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 regulations will be amended to clarify that immunization records shall be open to inspection by health department officials. Amendments are necessary to ensure children are protected to the extent possible from vaccine-preventable diseases and to protect the health of all Virginians. School officials must comply with the law, as stated in § 22.1-271.2 of the Code of Virginia, in regard to inspection of immunization records by health department officials. VDH annually reviews a random sample of school immunization records to ensure compliance with current requirements. VDH would also need to review school immunization records in the event of a vaccine-preventable disease outbreak. Local health department representatives have encountered increasing resistance from school officials. Most recently, at least three of the selected 600 sites initially refused to allow records to be reviewed as part of the annual immunization survey, despite instructions to de-identify records prior to review. If the proposed amendments are approved, failure to allow inspection of records could result in a decision to seek imposition of penalties (i.e. Class 1 misdemeanor) authorized by § 32.1-27 of the Code of Virginia.

Each year, the ACIP recommends changes to the immunization schedules that are subsequently published by the CDC and the AAP. The Regulations must also be amended to include the most recent schedules.

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?

Incorporating current statutory provision into the Virginia Administrative Code reinforces the duties of school admitting officials as currently required by law and does not change current practices.

Updating documents incorporated by reference is routine.

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.

Amendments to the regulations will:

- Clarify required activities of school officials
- Update references to the most current version of the immunization schedule

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 agency and the public are that amended regulations will help ensure that children are appropriately protected to the extent possible from vaccine preventable diseases. This also serves to protect the health of all Virginians. Proposed changes will clarify processes required for immunization record review and ensure that the most current recommendations are applied. No disadvantages to the public or the Commonwealth are anticipated.

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 applicable federal requirements. The proposed amendments are written in response to the Code of Virginia § 32.1-46 that requires children to be immunized and § 22.1-271 that defines school responsibilities.

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.

All localities in Virginia would be affected by the proposed amendments.

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 agency believes that the proposed amendment to the regulations is the least burdensome option to meet the requirements of the Code and comply with current immunization practices as recommended by the ACIP, the AAP and the American Academy of Family Physicians.

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>There will be very little, if any, fiscal impact as a result of the proposed amendments.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>There will be very little, if any, fiscal impact as a result of the proposed changes</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>No individuals or businesses not already subject to the current laws and regulations will be affected by these changes.</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,</p>	<p>All schools, including child care facilities and those with grades through 12 are included in the existing regulations. There are approximately 7,625 facilities including 5,012 licensed child care</p>

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.	facilities, 1,862 public schools and an estimated 750 private schools that are affected.
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.	The Department of Health projects no additional costs as a result of these amendments.
Beneficial impact the regulation is designed to produce.	Proposed changes are expected to clarify existing areas of concern and to reference the most current immunization schedules.

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.

Regulations are mandated by the Code of Virginia. The Agency believes the regulations provide the best alternative in response to the law.

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.

Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been

evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response

Not applicable

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.

Parents are required by the Code of Virginia to have their children immunized. All families benefit when children are age-appropriately immunized according to the most recent recommendations. These changes will not affect this benefit.

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 follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-110-10		Definition of “Immunization schedules” refers to an older version	Changes the reference from the 2015 schedules to 2017.
12VAC5-110-90		Discusses the responsibilities of admitting officials.	Adds a Section G describing the requirement that immunization records be open to inspection by health department officials.
12VAC 5- 110 Documents Incorporated by Reference		Current reference is to the 2015 recommended immunization schedules.	Updates the reference to the 2017 recommended schedules.

DEPARTMENT OF HEALTH
Update Immunization Schedules and Clarify Responsibilities of School Admitting Officials

Part I
Definitions

1 12VAC5-110-10. Definitions.

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

4 "Adequate immunization" means the immunization requirements prescribed under 12VAC5-
5 110-70.

6 "Admit" or "admission" means the official enrollment or reenrollment for attendance at any
7 grade level, whether full-time or part-time, of any student by any school.

8 "Admitting official" means the school principal or his designated representative if a public
9 school; if a nonpublic school or child care center, the principal, headmaster or director of the
10 school or center.

11 "Board" means the State Board of Health.

12 "Commissioner" means the State Health Commissioner.

13 "Compliance" means the completion of the immunization requirements prescribed under
14 12VAC5-110-70.

15 "Conditional enrollment" means the enrollment of a student for a period of 90 days
16 contingent upon the student having received at least one dose of each of the required vaccines
17 and the student possessing a plan, from a physician or local health department, for completing
18 his immunization requirements within the ensuing 90 calendar days. If the student requires more
19 than two doses of hepatitis B vaccine, the conditional enrollment period, for hepatitis B vaccine
20 only, shall be 180 calendar days.

21 "Documentary proof" means an appropriately completed copy of the most current version of
22 Form MCH 213G signed by a physician or his designee, registered nurse, or an official of a local
23 health department. A copy of the immunization record signed or stamped by a physician or his
24 designee, registered nurse, or an official of a local health department indicating the dates of
25 administration including month, day, and year of the required vaccines, shall be acceptable in
26 lieu of recording these dates on Form MCH 213G, as long as the record is attached to Form
27 MCH 213G and the remainder of Form MCH 213G has been appropriately completed. A
28 printout of an immunization record from the provider's electronic health record can be accepted

29 without a signature or stamp. For a new student transferring from an out-of-state school, any
30 immunization record, which contains the exact date (month/day/year) of administration of each
31 of the required doses of vaccines, is signed by a physician or his designee or registered nurse,
32 and complies fully with the requirements prescribed under 12VAC5-110-70 shall be acceptable.

33 "Immunization" means the administration of a product licensed by the FDA to confer
34 protection against one or more specific pathogens.

35 "Immunization schedules" means the ~~2015~~ 2017 Recommended Immunization Schedules
36 for Persons Aged 0 through 18 Years developed and published by the Centers for Disease
37 Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP), the
38 American Academy of Pediatrics (AAP), and the American Academy of Family Physicians
39 (AAFP).

40 "Physician" means any person licensed to practice medicine in any of the 50 states or the
41 District of Columbia.

42 "School" means:

- 43 1. Any public school from kindergarten through grade 12 operated under the authority of
44 any locality within this Commonwealth;
- 45 2. Any private or religious school that offers instruction at any level or grade from
46 kindergarten through grade 12;
- 47 3. Any private or religious nursery school or preschool, or any private or religious child
48 care center required to be licensed by this Commonwealth;
- 49 4. Any preschool classes or Head Start classes operated by the school divisions within
50 this Commonwealth; and
- 51 5. Any family day home or developmental center.

52 "Student" means any person who seeks admission to a school, or for whom admission to a
53 school is sought by a parent or guardian, and who will not have attained the age of 20 years by
54 the start of the school term for which admission is sought.

55 "Twelve months of age" means the 365th day following the date of birth. For the purpose of
56 evaluating records, vaccines administered up to four days prior to the first birthday (361 days
57 following the date of birth) will be considered valid.

Part IV

Procedures and Responsibilities

58 **12VAC5-110-90. Responsibilities of admitting officials.**

59 A. Procedures for determining the immunization status of students. Each admitting official or
60 his designee shall review, before the first day of each school year, the school medical record of

61 every new student seeking admission to his school, and that of every student enrolling in grade
62 six for compliance with the requirements prescribed in 12VAC5-110-70. Such review shall
63 determine into which one of the following categories each student falls:

64 1. Students whose immunizations are adequately documented and complete in
65 conformance with 12VAC5-110-70. Students with documentation of existing immunity to
66 mumps, measles, rubella, or varicella as defined in 12VAC5-110-80 B shall be
67 considered to be adequately immunized for such disease.

68 2. Students who are exempt from the immunization requirements of 12VAC5-110-70
69 because of medical contraindications or religious beliefs provided for by 12VAC5-110-
70 80.

71 3. Students whose immunizations are inadequate according to the requirements of
72 12VAC5-110-70.

73 4. Students without any documentation of having been adequately immunized.

74 B. Notification of deficiencies. Upon identification of the students described in subdivisions A
75 3 and 4 of this section, the admitting official shall notify the parent or guardian of the student:

76 1. That there is no, or insufficient, documentary proof of adequate immunization in the
77 student's school records.

78 2. That the student cannot be admitted to school unless he has documentary proof that
79 he is exempted from immunization requirements pursuant to 12VAC5-110-70.

80 3. That the student may be immunized and receive certification by a licensed physician,
81 registered nurse, or an official of a local health department.

82 4. How to contact the local health department to receive the necessary immunizations.

83 C. Conditional enrollment. Any student whose immunizations are incomplete may be
84 admitted conditionally if that student provides documentary proof at the time of enrollment of
85 having received at least one dose of the required immunizations accompanied by a schedule for
86 completion of the required doses within 90 calendar days, during which time that student shall
87 complete the immunizations required under 12VAC5-110-70. If the student requires more than
88 two doses of hepatitis B vaccine, the conditional enrollment period, for hepatitis B vaccine only,
89 shall be 180 calendar days. If a student is a homeless child or youth and does not have
90 documentary proof of necessary immunizations or has incomplete immunizations and is not
91 exempted from immunization as described in 12VAC5-110-80, the school administrator shall
92 immediately admit such student and shall immediately refer the student to the local school
93 division liaison, who shall assist in obtaining the documentary proof of, or completing,
94 immunizations. The admitting official should examine the records of any conditionally enrolled

95 student at regular intervals to ensure that such a student remains on schedule with his plan of
96 completion.

97 D. Exclusion. The admitting official shall, at the end of the conditional enrollment period,
98 exclude any student who is not in compliance with the immunization requirements under
99 12VAC5-110-70 and who has not been granted an exemption under 12VAC5-110-80 until that
100 student provides documentary proof that his immunization schedule has been completed,
101 unless documentary proof that a medical contraindication developed during the conditional
102 enrollment period is submitted.

103 E. Transfer of records. The admitting official of every school shall be responsible for sending
104 a student's immunization records or a copy thereof, along with his permanent academic or
105 scholastic records, to the admitting official of the school to which a student is transferring within
106 10 days of his transfer to the new school.

107 F. Report of student immunization status. Each admitting official shall, within 30 days of the
108 beginning of each school year or entrance of a student, or by October 15 of each school year,
109 file with the State Health Department through the health department for his locality, a report
110 summarizing the immunization status of the students in his school as of the first day of school.
111 This report shall be filed using the web-enabled reporting system or on the most current version
112 of Form SIS, the Student Immunization Status Report, and shall contain the number of students
113 admitted to that school with documentary proof of immunization, the number of students who
114 have been admitted with a medical or religious exemption and the number of students who have
115 been conditionally admitted.

116 G. Immunization records shall be open to inspection by health department officials.

117 ~~GH.~~ Each admitting official shall ensure that the parent or guardian of a female to be
118 enrolled in the sixth grade receives educational materials describing the link between the human
119 papillomavirus and cervical cancer. Materials shall be approved by the board and provided to
120 the parent or guardian prior to the child's enrollment in the sixth grade.

121 DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-110)

122 ~~2015 Recommended Immunization Schedules for Persons Aged 0 through 18 Years,~~
123 ~~Centers for Disease Control and Prevention, U.S. Department of Health and Human Services,~~
124 ~~effective January 1, 2015~~

125
126 [2017 Recommended Immunization Schedule for Children and Adolescents Aged 18 Years](#)
127 [or Younger, Centers for Disease Control, Health and Human Services, Effective January 1,](#)
128 [2017](#)